UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MASSACHUSETTS BRICKLAYERS & MASONS HEALTH AND WELFARE FUND, on Behalf of Itself and All Others Similarly Situated, Plaintiff, v. ENDO HEALTH SOLUTIONS, INC., ENDO PHARMACEUTICALS, INC., PENWEST PHARMACEUTICALS CO., and IMPAX LABORATORIES, INC., Defendants.	Civil Action No. COMPLAINT – CLASS ACTION JURY TRIAL DEMANDED

NATURE OF THE CLAIM

1. Massachusetts Bricklayers & Masons Health and Welfare Fund ("Plaintiff"), on behalf of itself and all others similarly situated, brings this class action for claims arising under federal and state antitrust laws and state common law to recover damages and equitable relief for the substantial injuries it and others similarly situated have sustained against Defendants Endo Health Solutions, Inc., Endo Pharmaceuticals, Inc. (together, "Endo"), Penwest Pharmaceuticals Co. ("Penwest"), and Impax Laboratories, Inc. ("Impax"), arising from Defendants' anticompetitive scheme to restrain competition in the market for extended release oxymorphone hydrochloride in the United States. Plaintiff's allegations are made on personal knowledge as to Plaintiff and Plaintiff's own acts and upon information and belief as to all other matters.

2. This antitrust action arises from Defendants' unlawful scheme to allocate and unreasonably delay competition in the market for extended release oxymorphone hydrochloride, which Endo sells under the brand name Opana ER. Defendants' anticompetitive conduct included a payment from Endo to Impax of more than $112 million in cash in exchange for Impax's agreement to keep its generic extended release oxymorphone hydrochloride out of the market for two and a half years – from June 2010 to January 2013. Endo used this period of delay that it bought from Impax to switch the market for Opana ER to a new formulation of Opana ER, Opana ER crush-resistant formulation ("Opana ER CRF"). But for Defendants' market allocation scheme, Impax would have launched its generic extended release oxymorphone hydrochloride as early as June 14, 2010 for 5, 10, 20, and 40 mg dosage strengths and July 22, 2010 for the 30 mg dosage strength when the FDA granted Impax final approval, and the vast majority of sales of those strengths would have gone to Impax's less expensive generic. As alleged below, Defendants' market allocation scheme injured Plaintiff and the Class

of consumers and third-party payors it seeks to represent (as defined below) by causing them to pay overcharges for their purchases of Opana ER.

3. Oxymorphone hydrochloride, an opioid used in the treatment of chronic pain, was first marketed and sold by Endo in the late 1950s but was later discontinued for commercial reasons. In the 1990s, Endo decided to revive tablet formulations of oxymorphone hydrochloride. However, Endo knew that the longest period of (non-patent) regulatory exclusivity that Endo could obtain for its revived tablet formulation of oxymorphone hydrochloride was three years. The original United States patent on oxymorphone hydrochloride itself was issued in the mid-1950s and expired long ago.

4. In order to obtain a longer period of exclusivity, Endo Pharmaceuticals, Inc. licensed four time-release patents from Penwest Pharmaceuticals Co. ("Penwest") and developed extended release oxymorphone hydrochloride tablets, which Endo named Opana ER. Endo listed the Penwest time-release patents in the FDA's Orange Book as covering Opana ER.

5. Endo then embarked on a strategy to block generic competition to Opana ER beyond three years by:

(a) Suing generic manufacturers, including Impax, Actavis South Atlantic LLC ("Actavis"), Sandoz, Inc. ("Sandoz"), Barr Laboratories, Inc. ("Barr"), Roxane Laboratories, Inc. ("Roxane"), and Watson Laboratories, Inc. ("Watson") – each of which sought to market generic extended release oxymorphone hydrochloride ("generic Opana ER") – for purportedly infringing the Penwest time release patents. These lawsuits triggered 30-month stays on the approval of these generic manufacturers' applications to market generic Opana ER.

(b) Ending its litigation with Impax – the first-filer potential generic competitor for the vast majority of Opana ER sales (the 5, 10, 20, 30, and 40 mg dosages) – by entering into a series of anticompetitive agreements (the "Exclusion Payment Agreements") whereby Impax agreed to keep its generic extended release oxymorphone hydrochloride off the market for two and a half years in exchange for a large future cash payment and other consideration from Endo. The Exclusion Payment Agreements contained two forms of payment to Impax: (1) A future cash payment of $102,049,000 from Endo to Impax should the sales of Opana ER in the quarter immediately prior to the delayed Impax launch date fall below a predetermined level; and (2) a cash payment from Endo to Impax of $10 million up front with an obligation to pay an additional $30 million – upon reaching certain predetermined milestones – under the guise of a development and co-promotion agreement for Impax's yet-to-be approved product to treat Parkinson's disease.

6. While the $102 million cash payment was conditioned on the sales of Opana ER falling below a certain level, the payment was all but guaranteed to occur because Endo had already planned on moving the prescription patterns away from Opana ER to a new crush-resistant formulation of Opana ER. Indeed, just one month after Endo ended its patent litigation with Impax, Endo filed a New Drug Application with the Food and Drug Administration ("FDA") for the approval of this new formulation of Opana ER called Opana ER CRF. After receiving FDA approval, Endo launched Opana ER CRF in the beginning of 2012 and set about converting all Opana ER prescriptions to Opana ER CRF.

7. The crush-resistant formulation made only minor alterations to the properties of the drug compound, and the FDA in its approval action to Endo recognized that Opana ER CRF was bioequivalent to Opana ER. Because of its bioequivalence, Opana ER or its generic equivalents offered "the same therapeutic benefits" as Opana ER CRF, permitting healthcare professionals to prescribe generic versions of Opana ER in lieu of Opana ER CRF for purposes of treatment.[1] Thus, as a secondary effort to help move the market away from Opana ER, Endo filed a Citizen Petition with the FDA petitioning it to withdraw marketing approval of the non-crush resistant Opana ER, as well as any application from a generic manufacturer that sought to make generic Opana ER. If successful, Endo could forestall the impact of generic Opana ER in the extended-release oxymorphone hydrochloride market. Impax reasonably anticipated (or in fact knew) of Endo's plans with respect to Opana ER and willingly negotiated and agreed to this $102 million "conditional" payment knowing that it was conditional in name only. From Impax's perspective, even if Endo's new crush-resistant formulation of Opana ER was successful in converting sales from Opana ER – thereby jeopardizing the marketing success of its generic Opana ER during Impax's 180-day exclusivity period – the bounty of the 180-day exclusivity had already been obtained through the $102 million cash payment.

8. Moreover, having secured an additional two and one-half years of its monopoly over the extended release oxymorphone hydrochloride market, Endo subsequently ended its patent litigations against Actavis, Sandoz, Barr, Roxane, and Watson.

[1] Letter from Janet Woodcock, M.D., Director, Ctr. For Drug Evaluation & Research, Food & Drug Admin., to Robert Barto, Vice President, Endo Pharmaceuticals Inc. (May 10, 2013), Docket No. FDA-2012-P-0895, at 8 ("Endo CP Final Decision"). Although the FDA determined that Opana ER offered the same therapeutic benefits as Opana ER CRF, the FDA has not officially determined that generic versions of Opana ER are "AB" rated generic equivalents of Opana ER CRF, which would permit pharmacies to automatically substitute generic Opana ER with Opana ER CRF.

9. The Exclusion Payment Agreements effectively created a "bottleneck" whereby no other generic manufacturer could come to market until after Impax had been on the market for 180 days with generic versions of 5 mg, 10 mg, 20 mg, 30 mg, and 40 mg Opana ER tablets.

10. Endo paid Impax to stay out of the market for two and a half years to protect Endo's stream of monopoly profits. But for Endo's unlawful, large payment, Impax would have launched its generic earlier than it finally did: (a) "at-risk" (that is, while the patent litigation was still pending), or (b) after winning the patent suit, or (c) via a lawful settlement agreement *without* a large payment from Endo to Impax. Endo literally bought itself freedom from generic competition. Endo and Impax conspired to allocate the market for Opana ER and its generic equivalents in a manner that allowed them to share monopoly rents at the expense of purchasers of Opana ER.

11. But for the Exclusion Payment Agreements, generic versions of 5 mg, 10 mg, 20 mg, and 40 mg Opana ER would have been available as early as June 14, 2010, when the FDA granted final approval for those dosage strengths of Impax's generic Opana ER, and a generic version of 30 mg Opana ER would have been available as early as July 22, 2010, when Impax received final approval for that strength. Plaintiff and members of the Class would have substituted the less expensive generic versions for their purchases of brand Opana ER long before Impax belatedly launched its generic in January 2013.

12. Defendants' Exclusion Payment Agreements were designed to and did in fact: (a) delay the entry of less expensive, AB-rated generic Opana ER; (b) fix, raise, maintain or stabilize the price of Opana ER and AB-rated generic Opana ER; and (c) allocate nearly 100% of the U.S. market for Opana ER and its AB-rated generic equivalents to Endo for at least two and one half years.

13. Plaintiff brings this action as a class action on behalf of all consumers and third-party payors in certain states, the District of Columbia, and Puerto Rico who indirectly purchased, paid and/or provided reimbursement for brand and/or generic Opana ER, other than for re-sale since June 14, 2010.

THE PARTIES

14. Plaintiff Massachusetts Bricklayers & Masons Health and Welfare Fund is based in Boston, Massachusetts and provides health and welfare benefits to active and retired members who work or worked in Massachusetts, Maine, New Hampshire and Rhode Island. During the Class Period, Plaintiff purchased and/or paid for some or the entire purchase price for Opana ER. Plaintiff paid and/or reimbursed more for Opana ER than it would have absent Defendants' anticompetitive conduct to delay generic entry and was injured as a result of such conduct.

15. Defendant Endo Health Solutions, Inc. is a Delaware corporation with its principal place of business at 1400 Atwater Drive, Malvern, Pennsylvania, 19355. Until May 2012, Endo Health Solutions, Inc. was known as Endo Pharmaceuticals Holdings, Inc.

16. Defendant Endo Pharmaceuticals, Inc. is a wholly-owned subsidiary of Endo Health Solutions, Inc. Endo Pharmaceuticals, Inc. is a Delaware corporation with its principal place of business at 1400 Atwater Drive, Malvern, Pennsylvania, 19355.

17. Defendant Penwest Pharmaceuticals Co. is a pharmaceutical company with its principal place of business at 2981 Route 22, Suite 2, Patterson, New York, 12563. Penwest was acquired by Endo Pharmaceuticals Holdings, Inc. on November 4, 2010 for $144 million. Prior to November 4, 2010, Endo Pharmaceuticals, Inc. and Penwest developed and marketed Opana ER together. Penwest was previously known as Edward Mendell Co.

18. Defendant Impax Laboratories, Inc. is a Delaware corporation with its principal place of business at 30831 Huntwood Avenue, Hayward, California, 94544. Impax is a

technology-based specialty pharmaceutical company utilizing its core competency in drug delivery and formulation expertise.

19. Endo, Penwest, and Impax are referred to collectively as "Defendants."

20. All of Defendants' actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, or with the actual, apparent, or ostensible authority of Defendants.

JURISDICTION AND VENUE

21. Plaintiff brings this action under Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15 and 26, to obtain injunctive relief and costs of suit, including attorneys' fees, against Defendants for the injuries that Plaintiff and the other members of the Class have suffered from Defendants' violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

22. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1337 and Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15(a) and 26, because this action arises under the federal antitrust laws. This Court also has supplemental jurisdiction over state law claims pursuant to 28 U.S.C. § 1367(a).

23. This Court has jurisdiction over this matter under 28 U.S.C. § 1332(d) because this action is a class action in which the aggregate amount in controversy for the proposed class exceeds $5,000,000, and at least one member of the putative class is a citizen of a state different from that of one of Defendants.

24. Venue is proper in this District under 28 U.S.C. § 1391(b), (c) and (d) and Sections 4 and 12 of the Clayton Act, 15 U.S.C. §§ 15(a) and 22, because, during the Class

Period, Defendants resided, transacted business, were found, or had agents within this District, and a portion of the affected interstate trade and commerce discussed below was carried out in this District.

25. Defendants' conduct, as described in this Complaint, was within the flow of, was intended to, and did have a substantial effect on, the interstate commerce of the United States, including in this District.

26. During the Class Period, Endo manufactured, sold and shipped Opana ER in a continuous and uninterrupted flow of interstate commerce. The conspiracy in which Defendants participated had a direct, substantial, and reasonably foreseeable effect on interstate commerce.

27. During the Class Period each Defendant, or one or more of its affiliates, used the instrumentalities of interstate commerce to join or effectuate their conspiracy.

REGULATORY AND ECONOMIC BACKGROUND

28. Generic competition allows purchasers at all levels of the pharmaceutical chain of distribution to purchase both brand drugs and their generic equivalents at reduced prices. Generic competition to a single brand drug can provide potentially billions of dollars in savings to consumers, pharmacies, and other drug purchasers, as well as to private health insurers or state Medicaid programs, both of which reimburse the cost of drug purchases by covered individuals.

29. The FDA sets the standards for the approval of generic drugs. Upon satisfaction of FDA regulations governing, among other things, safety, efficacy, and labeling, the FDA confers upon a generic drug an "AB" rating. The AB rating signifies that the generic version is, for all intents and purposes, bioequivalent[2] to its brand counterpart.

[2] Bioequivalence is defined as

> the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents

30. The AB rating permits the generic drug to be substituted for the brand drug at a pharmacy counter. All States permit – and indeed, some States require – pharmacists to substitute an AB-rated generic drug for the corresponding brand drug, unless the prescribing healthcare provider has specifically stated that the brand drug is to be used.

31. Many health insurers and other third-party payors have adopted policies to encourage the substitution of AB-rated generic drugs for their brand name counterparts. For example, many third-party payors implement a tiering system that places certain drugs on different benefit tiers. A drug that is placed on one tier may receive only partial reimbursement, while a drug placed on another tier may receive full reimbursement. Typically, branded drugs are usually placed on a different tier than their corresponding generic. Furthermore, branded drugs with a generic equivalent are usually subject to smaller reimbursements or higher co-pays, while generic drugs will be given total (or near total) reimbursement with limited or no co-pay.

32. As a result of these policies, healthcare professionals are incentivized to prescribe generics so that they can receive higher reimbursements. In addition, these policies also incentivize end-users to request generic drugs because of the cost-savings they may receive with respect to their co-pay.

33. Because both healthcare professionals and end-users are economically incentivized to prefer generic drugs, AB-rated generics are usually able to capture a substantial portion of the market.

34. The first AB-rated generic is typically priced at a discount to its brand counterpart. As additional AB-rated generics obtain FDA approval to enter the market, the

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> or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study.

21 C.F.R. § 320.1(e).

resulting increase in competition causes prices of both the first generic and the brand counterpart to drop dramatically.

35. Empirical studies have shown that within a year of generic entry, generics will have obtained about 90% of the market, *i.e.*, pharmacists fill 90 of every 100 prescriptions for the compound with an AB-rated generic. Indeed, an FTC study found that in a "mature generic market, generic prices are, on average, 85% lower than the pre-entry branded drug prices."[3]

A. The FDA New Drug Approval Process

36. The Federal Food, Drug and Cosmetic Act (the "FDCA") and its accompanying regulations set the standards for the approval of any new drug compound that is to be marketed, sold, or distributed in the United States. Drug manufacturers seeking to gain FDA approval for a new drug must file a New Drug Application ("NDA"). Applicants filing an NDA are required to provide a host of information demonstrating the safety and efficacy of their drug, including, but not limited to: (1) information and studies regarding the chemistry of the drug substance, which includes information concerning how the drug is manufactured; (2) information and studies regarding nonclinical pharmacology and toxicology for the new drug; (3) information and studies regarding the human pharmacokinetics and bioavailability; and (4) information and data from clinical studies on human subjects.[4]

37. Upon satisfying FDA regulations concerning efficacy, safety and labeling, the FDA will approve the NDA, permitting the applicant to market, sell, and distribute the approved drug to the U.S. public.

[3] FTC Staff Study, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions, at 8 (Jan. 2010), available at http://emmanuelcombe.org/delay.pdf.

[4] *See* 21 C.F.R. § 314.50(c)-(d).

38. In addition, upon receiving FDA approval, the brand manufacturer will list any patents it believes cover the approved drug in a publication called the "Approved Drug Products with Therapeutic Equivalence Evaluations," which is more commonly referred to as the "Orange Book."[5]

39. However, there are limitations on the types of patents that can be listed. Only drug substance patents (active ingredient), drug product patents (formulation and composition), and method-of-use patents qualify for listing in the Orange Book.[6] Thus, for example, process patents covering a new drug are not eligible for listing in the Orange Book (however, they may be asserted in a future patent litigation against any allegedly infringing product).

40. In listing patents in the Orange Book, the FDA acts in a ministerial capacity. It does not verify whether the patents listed in the Orange Book are properly listed, and instead relies on the accuracy and truthfulness of the NDA applicant.

41. In addition to the protection conferred by patents covering the brand manufacturer's drug, NDA applicants are afforded additional statutory protections for a drug containing a new active ingredient. NDAs for drugs containing a new active ingredient are given up to five years of marketing exclusivity before any generic drug manufacturer may file an application for the approval of a generic formulation.[7]

B. The Hatch-Waxman Amendments to the FDCA Encourage and Facilitate the Approval of Generic Drugs

42. In 1984, Congress amended the FDCA with the enactment of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), more commonly known as the "Hatch-Waxman Amendments."

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[5] 21 U.S.C. § 355(j)(7)(A)(iii).

[6] 21 C.F.R. § 314.53(b).

[7] 21 U.S.C. § 355(j)(5)(F)(ii).

43. The Hatch-Waxman Amendments simplify the regulatory hurdles that generic drug manufacturers have to clear prior to marketing and selling generic drugs. Instead of filing a lengthy and highly costly NDA, the Hatch-Waxman Amendments allow generic drug manufacturers to obtain FDA approval in an expedited fashion through the filing of an Abbreviated New Drug Application ("ANDA").

44. If an ANDA applicant shows that the generic drug is bioequivalent to the brand drug, then the ANDA applicant may rely on scientific and other data compiled in the brand drug NDA it references concerning, among other things, safety and efficacy.[8] The ability to rely on the scientific data published in the referenced NDA obviates the need for duplicative and expensive experimentation and clinical trials, which in some instances can result in out-of-pocket costs of upwards of $130 million.[9] The FDA must approve an ANDA unless the information submitted in the ANDA is insufficient to meet the requirements under the Hatch-Waxman Amendments.[10] In sum, the streamlined approval process under the Hatch-Waxman Amendments makes it easier for generic drug manufacturers to bring competing and cheaper generic products to market.

45. Although the Hatch-Waxman Amendments seek to facilitate generic competition, the brand manufacturer retains the right to enforce any patents associated with its brand drug. As part of its ANDA, the applicant must certify that the generic drug will not infringe any of the Orange Book patents because: (1) no patents exist on the brand drug; (2) the patents have expired; (3) the patents will expire by the time the generic product comes to market; or (4) the

[8] 21 U.S.C. § 355(j)(2)(A).

[9] *See* C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1564 n.36 (2006).

[10] 21 U.S.C. § 355(j)(4).

patents are invalid, unenforceable, or will not be infringed by the sale of the generic product.[11] When a generic drug manufacturer certifies that the patents covering the referenced brand drug are invalid, unenforceable, or will not be infringed, it known as a "Paragraph IV certification."

46. When a generic drug manufacturer files a Paragraph IV certification asserting that one or more patents listed in the Orange Book are invalid, unenforceable or will not be infringed, it must serve notice of its certification to both the brand manufacturer and the owner(s) of the patent.

47. The issuance of a Paragraph IV certification creates an "artificial act" of patent infringement, permitting the patent owner to file a patent infringement suit against the ANDA applicant making the Paragraph IV certification(s).[12]

48. If the brand manufacturer files a patent infringement suit against the ANDA applicant within 45 days of receiving the Paragraph IV certification, the FDA may not grant final approval to the ANDA until the earlier of: (a) 30 months; or (b) a court ruling that the patent is invalid, unenforceable, or not infringed by the ANDA.[13] During the 30-month stay, the FDA may grant "tentative approval" of an ANDA if the FDA determines that the ANDA would otherwise qualify for final approval, but for the 30-month stay.

49. Despite the threat of a patent infringement suit and a 30-month stay, the Hatch-Waxman Amendments create powerful incentives for generic drug manufacturers to file ANDAs. Specifically, the Hatch-Waxman Amendments grant a 180-day period of market

[11] 21 U.S.C. § 335(j)(2)(A)(vii)(I)-(IV).

[12] 35 U.S.C. § 271(e)(2)(A).

[13] 21 U.S.C. § 355(j)(5)(B)(iii). The 30-month stay is in some instances a misnomer because it can last more than three years. The 30 months is measured from the innovator's receipt of notice, provided that notice is received by the innovator no earlier than the point five years after the innovator's marketing approval. *Id.* Thus, if a generic drug manufacturer files a Paragraph IV certification during its first year of eligibility – *i.e.*, between the fourth and fifth year after the NDA's approval – then the 30-month stay will not begin until the start of the fifth year after the NDA's approval. 21 U.S.C. § 355(j)(5)(F)(ii). *See also* Hemphill, *supra* note 10, at 1566 n.50.

exclusivity to the first applicant (the "first-filer") to file a substantially complete ANDA containing a Paragraph IV certification.

50. During the 180-day period of market exclusivity, the first-filer only competes against the brand manufacturer and potentially any AG marketed under the brand manufacturer's NDA; all other generic ANDA applicants must wait until either the expiration of the 180-day exclusivity period or a court order finding that each of the patents that are the subject of a Paragraph IV certification are invalid, unenforceable, or not infringed.

51. Because all other ANDA generics are barred from the market during the first-filer's 180-day exclusivity period, the first-filing ANDA applicant is able to price its generic version at a price slightly below the brand drug's price. This allows the first-filer to gain market share, while simultaneously taking advantage of the price umbrella created by the brand manufacturer's pricing. In addition, this pricing strategy effectively allows the first-filer to share the monopoly profits that previously were held exclusively by the brand manufacturer.

52. However, once the first-filer's 180-day exclusivity period expires, all other FDA-approved ANDA filers can begin to market their generic equivalents, driving down prices substantially and reducing the profitability of both the branded drug and the first-filer's generic.

C. Brand Manufacturers and First-Filers' Manipulate the Regulatory Structure to Delay the Emergence of Generic Competition

53. Because the Hatch-Waxman Amendments automatically stay the approval of an ANDA when a brand manufacturer files an infringement suit against an ANDA applicant, the brand manufacturers have an incentive to liberally (and sometimes wrongfully) list in the Orange Book all patents potentially covering the brand drug. Upon a generic drug manufacturer's filing of an ANDA with a Paragraph IV certification, the brand manufacturer will then sue on one or more of those Orange Book patents to trigger the stay.

54. Frequently, patent infringement suits arising from Paragraph IV certifications result in settlements. In some of these settlements, the brand manufacturer will offer the generic drug manufacturer some form of consideration (*i.e.*, payment) in exchange for the generic drug manufacturer agreeing to delay entry of its generic product. These settlements commonly are referred to as "pay-for-delay agreements."

55. These pay-for-delay agreements have the practical effect of permitting the settling brand manufacturer to retain a significant portion of its monopoly profits, while only ceding a relatively small portion of those profits to the settling generic drug manufacturer in exchange for the generic drug manufacturer's agreement to delay market entry.

56. The incentive to create these types of agreements is particularly acute between a brand manufacturer and the first-filing ANDA applicant. In these agreements, the brand manufacturer seeks to delay generic entry and preserve its monopoly for as long as possible. Typically, a generic drug manufacturer will want as early an entry date as possible, if only for the higher present value of earlier sales.

57. However, unlike other generic drug manufacturers, a first-filing ANDA applicant has the potential benefit of 180 days of marketing exclusivity where it can reap substantial revenues as potentially one of two products in the relevant drug market. A first-filing ANDA applicant's continued litigation against the brand manufacturer runs the risk that the court will find the patent(s) at issue valid, enforceable, and/or infringed by the first-filer's ANDA. A finding of validity, enforceability, and/or infringement by a court would negate the first filer's Paragraph IV certification and disqualify that generic drug manufacturer from receiving the benefit of 180 days of marketing exclusivity. Thus, the first-filer has an acute interest in settling

the patent infringement lawsuit as a means of guaranteeing its 180-day exclusivity period, and, in turn, the economic bounty associated with it.

58. With the promise of substantial revenue during its generic exclusivity secure, the first-filer can be made indifferent to any delayed launch sought by the brand manufacturer, so long as the brand name manufacturer sufficiently compensates the first-filer for the delay in launching its generic.

59. Moreover, brand manufacturers are willing to over-compensate the first-filer for any delay in generic launch in exchange for the promise that the first-filer will not enter before a certain date. This is because the value of monopoly profits is so great that the brand manufacturer is willing to pay more to ensure the first-filer's acquiescence to the later launch date. The generic drug manufacturer's acquiescence to a later entry date, in turn, preserves a substantial portion of the brand manufacturer's monopoly profits in the period prior to the first-filer's agreed-to launch date.

60. In essence, by settling with the brand manufacturer, the first-filer receives a double bonus in the form of: (1) a substantial payment from the brand manufacturer to forgo early entry; and (2) the guaranteed retention of shared monopoly profits during the first-filer's 180-day exclusivity period. Under such circumstances, the first-filing ANDA applicant has limited incentive to continue the patent litigation for purposes of securing a judgment of non-infringement, invalidity, or unenforceability – and thus, a potentially earlier entry date – because it still retains the economic bounty associated with its statutory 180-day exclusivity period.

61. Such pay-for-delay agreements also create powerful disincentives for subsequent ANDA filers to continue defending their ANDAs in patent infringement litigations against the brand manufacturer. Specifically, once it becomes apparent that the brand manufacturer and the

first-filer have settled their patent litigation, subsequent ANDA filers usually will not pursue litigation aggressively, and, often times, settle as well.

62. Subsequent ANDA filers are unlikely to continue litigating because obtaining a judgment that the patents subject to Paragraph IV certifications are invalid, unenforceable, or not infringed provides little pay-off to the subsequent ANDA filer. For example, prior to the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA"), Pub. L. No. 108-173, 117 Stat. 2066, a judgment of patent invalidity or unenforceability would not cause the first-filer to lose its 180-day exclusivity period; rather, the subsequent filer's success in litigation would only accelerate the start of the first-filer's exclusivity period. The subsequent ANDA filer must still wait until after the first-filer's 180-day exclusivity period expires, and it is only at that point when other FDA-approved ANDA applicants can enter the market as well. Thus, these pay-for-delay agreements effectively "park" exclusivity and cause a bottleneck in the timing of full generic entry.

63. More recent legislation has not alleviated the problems caused by pay-for-delay agreements. The MMA attempts to make the incentives underlying pay-for-delay agreements less attractive by enumerating a series of forfeiture events that, if triggered, will deprive a first-filer of its 180-day exclusivity period.

64. For instance, one of the key forfeiture events under the MMA is a "failure-to-market" by the first-filer.[14] A first-filer ANDA applicant forfeits its 180-day exclusivity period if it fails to market the drug by the later of:

(a) The earlier of:

(i) 75 days after final approval or

[14] 21 U.S.C. § 505(j)(5)(D)(i)(I).

(ii) 30 months after ANDA submission; **or**

(b) The date that is 75 days after the date as of which, as to each of the patents that qualified the first-filer for exclusivity (*i.e.*, the filing of a Paragraph IV certification), at least one of the following has occurred:

(i) A final decision of invalidity or non-infringement;

(ii) A settlement order entering final judgment that includes a finding that the patent is invalid or not infringed; or

(iii) The NDA holder delists the patents subject to the first-filer's Paragraph IV certification from the Orange Book.

65. While noble in purpose, scholars have found the MMA's "use it or lose it" provision to be woefully inadequate in deterring anticompetitive agreements to delay generic competition for two reasons. First, market acceleration clauses, which are standard components of pay-for-delay agreements, allow the first-filer to accelerate its entry into the market ahead of the later date agreed to with the brand manufacturer in its settlement should a subsequent generic challenger prevail in the courts.

66. Second, brand manufacturers can avoid triggering a potential forfeiture event by only suing on some, but not all, of the patents subject to the first-filer's Paragraph IV certifications. Because a subsequent filer needs to obtain a judgment of invalidity or non-infringement with respect to **all** patents that are the subject of a first-filer's Paragraph IV certification in order to trigger the forfeiture event, the brand manufacturer need only sue on a few of the patents to avoid that scenario.

67. The lengthy and expensive nature of patent litigation makes it such that subsequent filing generic drug manufacturers will not have the stomach to pursue litigation to the

end. Indeed, by the time a generic drug manufacturer secures the judgments necessary, "the clock [will] simply run[] out on the subsequent generic filers fighting to open the market earlier than the date agreed to by the first filer in its 'parked' exclusivity settlement."

FACTUAL ALLEGATIONS

A. Background on Oxymorphone Hydrochloride and Endo's Early Efforts at Marketing the Drug Compound

68. Oxymorphone hydrochloride is an opioid indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate."[15] The primary ingredient in oxymorphone hydrochloride – oxymorphone – is a highly addictive morphine-like compound that is subject to abuse and misuse. Because oxymorphone is subject to abuse and misuse, the Drug Enforcement Agency ("DEA") has listed it as a Schedule II controlled substance, which limits the amount of oxymorphone hydrochloride any one manufacturer can produce in single year.[16] At or near the end of each calendar year, the DEA publishes in the Federal Register quotas for the amount of oxymorphone permissible for conversion or sale.

69. Oxymorphone was first developed in Germany in 1914. Some 40 years later, Endo received FDA approval for Oxymorphone IR ("immediate release") in 1959, but was removed from the market for commercial reasons sometime thereafter.[17]

70. In the 1990s, Endo decided to seek FDA approval to re-launch a tablet form of oxymorphone hydrochloride. Endo was aware that because oxymorphone hydrochloride was a previously-approved molecule, it would not be eligible for the five years of regulatory

[15] http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=557e9610-62d7-42bf-90c1-44215bd8c1f8#section-12.1

[16] Drug Enforcement Agency, Office of Diversion Control, http://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf.

[17] http://www.accessdata.fda.gov/drugsatfda_docs/nda/2006/021610s000_021611s000_MedR_P2.pdf (p.37)

exclusivity awarded to approval of "New Molecules." Instead, at most, Endo could be eligible for three years of regulatory exclusivity if Endo submitted new clinical studies in support of its NDA. Indeed, Endo recognized this when it submitted its patent information and exclusivity forms to the FDA in December 17, 2002 – with respect to each of the patents mentioned in the form, it only sought three years of exclusivity from the date the FDA issued final approval of its NDA for Opana ER.

B. Endo Acquires Additional Patent Protection from Penwest

71. Prior to Endo's submission of its NDA for Opana ER, Endo purchased from Penwest the rights to patents that it could use to block generic entry beyond those three years. As such, on September 17, 1997, Endo entered into a collaboration agreement with Penwest to exclusively co-develop opioid analgesic products using Penwest's patents. Penwest possessed several patents related to time-release formulations for drug tablets (not to be confused with patents on the drug molecules themselves, known as "compound patents"). In the 1990s, Penwest (then known as Edward Mendell Co.) obtained patents related to time release formulations: United States Patent No. 5,128,143 entitled "Sustained release excipient and tablet formulation" ("the '143 patent"); United States Patent No. 5,958,456 entitled "Controlled release formulation (albuterol)" ("the '456 patent"); and United States Patent No. 5,662,933 entitled "Controlled release formulation (albuterol)" ("the '933 patent").

72. In 2002, Penwest also filed the application for what ultimately issued as United States Patent No. 7,276,250 patent entitled "Sustained release formulations of oxymorphone hydrochloride" ("the '250 patent").

73. The '143, '456, '933, and '250 patents (collectively, the "Penwest time-release patents") were set to expire in 2008, 2013, 2013, and 2023, respectively.[18]

74. Penwest licensed the Penwest time-release patents to Endo soon afterwards.

75. Endo began selling Opana ER on or about July 21, 2006. Opana ER was originally approved and marketed in 5 mg, 10 mg, 20 mg, and 40 mg tablets.

76. In March 2008, the FDA approved three additional dosage strengths of Opana ER: 7.5 mg, 15 mg, and 30 mg. Endo began selling those strengths of Opana ER on April 1, 2008.

77. Based upon Endo having conducted new clinical studies, Endo was awarded three years of regulatory Endo exclusivity (preventing the FDA from approving any generic versions for three years) for all strengths of Opana ER through June 22, 2009, after which Endo's Opana ER monopoly would be subject to generic competition.

78. However, prior to its first sales of Opana ER, Endo only listed the '143 patent in the Orange Book, a patent that was set to expire in 2008. Because Opana ER's three-year clinical exclusivity would run in June 2009, Endo knew it needed additional protection to maintain their monopoly over Opana ER. Thus, over a year after it made its first commercial sales of Opana ER, Endo late-listed the '250, '456, and '933 patents in the Orange Book, in violation of 21 C.F.R. § 314.53.[19]

79. In doing, Endo effectively forced all would-be ANDA filers to file paragraph IV certifications in connection with each of these patents if they sought to market their generic

[18] http://www.wikinvest.com/stock/Penwest_Pharmaceuticals_(PPCO)/Actavis_Anda_Litigation

[19] As required by 21 C.F.R. § 314.53, brand drug manufacturers are required to declare all patents "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product" for listing in the Orange Book within 30 days of filing an NDA.

product before those patents expired. This in turn would permit Endo to sue for patent infringement and trigger the operation of the statutory 30-month stay under the Hatch-Waxman Amendments, delaying FDA approval of any filed ANDA by at least two and one-half years and preserving its monopoly over the extend-release oxymorphone hydrochloride market during that time.

C. Endo and Penwest Sue Impax For Patent Infringement

80. Impax filed ANDA 79-087 for its generic extended release oxymorphone hydrochloride in June 2007. However, because of deficiencies within the ANDA, the FDA rescinded its acceptance of the application and requiring Impax to resubmit the application.

81. On or prior to October 2, 2007, Impax resubmitted ANDA 79-087 and included a Paragraph IV certification stating that Impax's proposed generic extended release oxymorphone hydrochloride tablets in 5 mg, 10 mg, 20 mg, and 40 mg strengths did not infringe the '250, '456, or '933 patents. On October 2, 2007, Impax sent to Penwest and Endo a Paragraph IV Notice explaining that it had submitted ANDA 79-087 seeking approval to manufacture, use, or sell generic extended-release oxymorphone hydrochloride tablets prior to the expiration of the '250 patent. Additional notices with respect to the '250 patent were sent to Endo on October 3, 4, 5, and 9, 2007. In addition, on October 29, 2007, Impax sent Penwest and Endo Paragraph IV Notices with respect to the '933 and '456 patents.

82. On November 15, 2007, Penwest and Endo sued Impax for declaratory judgment in the United States District Court for the District of Delaware, 1:07-cv-00731-KSH, seeking a declaration that Impax's previous Paragraph IV notices null and void because Penwest and Endo claimed that Impax did not have an acceptable ANDA on file with the FDA. Penwest and Endo also sued Impax for infringement of the '456 and '933 patents. Impax asserted affirmative defenses and counterclaimed that the '456 and '933 patents were invalid because they failed to

comply with "one or more provisions of Title 35 of the United States Code [patents], including but not limited to, utility, anticipation, obviousness, lack of enablement, lack of written description and indefiniteness" or were invalid due to double-patenting.

83. On December 12, 2007, the FDA advised Impax that its ANDA 79-087 "has been deemed acceptable for filing and substantive review by FDA as of November 23, 2007."

84. On December 14, 2007, Impax resent notices to Penwest and Endo stating that it had submitted ANDA 79-807 seeking approval to manufacture, use, or sell generic extended release oxymorphone hydrochloride tablets prior to the expiration of the '250, '456, and '933 patents. The December 13, 2007 notice also advised Penwest and Endo that Impax's ANDA 79-087 included a Paragraph IV certification that the proposed manufacture, importation, use or sale of the generic extended release oxymorphone hydrochloride tablets described in Impax's ANDA 79-087 would not infringe any claim of the '250, '456, or '933 patents.

85. Upon resubmission of these Paragraph IV Notices to Penwest and Endo, Penwest and Endo sued Impax on January 25, 2008 in the United States District Court for the District of Delaware for infringement of the '456 and '933 patents—but not for the '250 patent. By filing this lawsuit, Penwest and Endo triggered the automatic 30-month stay under the Hatch-Waxman Amendments, through mid-June 2010, during which time the FDA could not approve Impax's ANDA 79-087 for 5 mg, 10 mg, 20 mg, and 40 mg generic Opana ER. Impax again asserted affirmative defenses and counterclaimed that the '456 and '933 patents were invalid.

86. Impax was the first generic company to file an ANDA with a Paragraph IV certification as against the '250, '456, and '933 patents for the 5 mg, 10 mg, 20 mg, and 40 mg strengths of Opana ER. This meant that Impax, as first-filer, was entitled to 180 days of exclusivity for those strengths as against other ANDA filers. As such, by delaying Impax's entry

into the market, Penwest and Endo could delay all generics competitors from entering the market for the 5 mg, 10 mg, 20 mg, and 40 mg strengths of Opana ER.

87. With the Impax patent litigation pending, in March 2008, the FDA approved three additional dosage strengths of Opana ER: 7.5 mg, 15 mg, and 30 mg. Endo launched those strengths of Opana ER on April 1, 2008.

88. Soon thereafter, on June 13, 2008, Impax sent Penwest and Endo a notice stating that Impax had filed an amendment to ANDA 79-087 to include the 7.5 mg, 15 mg, and 30 mg strengths. The June 13, 2008 notice also advised Penwest and Endo that Impax's amended ANDA included a Paragraph IV certification that the proposed manufacture, importation, use or sale of the generic extended-release oxymorphone hydrochloride described in its ANDA would not infringe either the '456 or '933 patents.

89. Impax was the first Paragraph IV filer against the '250, '456, and '933 patents for the 30 mg strength of Opana ER. As a result, Impax was entitled to a period of 180 days of marketing exclusivity for the 30 mg strength of generic Opana ER (as discussed below, Actavis was the first filer for the 7.5 mg and 15 mg strengths of generic Opana ER).

90. On July 25, 2008, Endo filed a third lawsuit against Impax in the United States District Court for the District of Delaware alleging that Impax's amendment to its ANDA covering the 7.5 mg, 15 mg, and 30 mg tablets of generic Opana ER infringed the '456 and '933 patents (but not the '250 patent). Impax again asserted affirmative defenses and counterclaims that the '456 and '933 patents were invalid. In addition, Impax claimed that Penwest and Endo engaged in inequitable conduct before the United States Patent and Trademark Office ("PTO") in connection with the prosecution of the '456 and '933 patents by intentionally failing to disclose

various pieces of prior art that would have rendered the claims in the '456 and '933 patents unpatentable.

91. In February 2009, the lawsuits that Endo filed against Impax relating to Opana ER were consolidated and transferred to the United States District Court for the District of New Jersey under the lead docket number 09-831 (the "Impax Patent Litigation").

D. Penwest and Endo sue other Generic Manufacturers Submitting ANDAs for Opana ER

92. Penwest and Endo sued subsequent generic ANDA filers for extended release oxymorphone hydrochloride as well.

1. Actavis Patent Infringement Suit

93. In February 2008, Penwest and Endo received a notice from Actavis stating that Actavis had submitted ANDA 79-046 seeking approval to manufacture, use, or sell generic extended release oxymorphone hydrochloride 5 mg, 10 mg, 20 mg, and 40 mg tablets prior to the expiration of the '250, '456 and '933 patents. Actavis' notice advised Penwest and Endo that Actavis's ANDA 79-046 included a Paragraph IV certification that the proposed manufacture, importation, use, or sale of the generic extended release hydrochloride tablets described in Actavis's ANDA would not infringe any claim of the '250, '456, or '933 patents and that the claims in those patents are invalid.

94. On March 28, 2008, Penwest and Endo sued Actavis in the United States District Court for the District of New Jersey, No. 2:08-cv-01563, alleging infringement of only the '456 patent (it did not sue for the '250 or '933 patents). By filing this suit, Endo triggered the automatic 30-month stay during which the FDA could not approve Actavis' ANDA for 5 mg, 10 mg, 20 mg, and 40 mg generic Opana ER until August 2010 at the earliest.

95. On or around May 29, 2008 (covering 7.5 mg and 15 mg Opana ER) and June 30, 2008 (covering 30 mg Opana ER), Actavis sent Paragraph IV Notices to Penwest and Endo informing it that Actavis had amended its ANDA to include the new dosage strengths of Opana ER and that the Actavis generic Opana ER would not infringe the '250, '456, or '933 patents and that the claims in those patents are invalid.

96. Actavis was the first generic company to file a Paragraph IV certification with respect to the patents that Endo listed for the 7.5 mg and 15 mg strengths of Opana ER, and therefore Actavis was entitled to a period of 180 days of market exclusivity upon final FDA approval against other ANDA filers (as alleged above, Impax was the first filer for all other dosage strengths). The 7.5 mg and 15 mg strengths, however, constitute a very small part of Opana ER sales, accounting for less than 10%.

97. On July 11, 2008, Penwest and Endo filed a second suit against Actavis in the United States District Court for the District of New Jersey alleging infringement of the '456 patent only (not the '250 or '933 patents), triggering the 30-month automatic stay under the Hatch-Waxman Amendments with regard to the 7.5 mg, 15 mg, and 30 mg strengths of Actavis's generic Opana ER.

98. The Actavis suits were later consolidated in the United States District Court for the District of New Jersey under the lead docket number 08-1563 (the "Actavis Patent Litigation").

2. Sandoz Patent Infringement Suit

99. On or about July 9, 2008, Sandoz sent a Paragraph IV Notice to Penwest and Endo with regard to Sandoz's ANDA 90-565 covering generic Opana ER in 5 mg, 10 mg, 20 mg, and 40 mg dosage strengths, explaining that the Sandoz generic would not infringe the '250, '456 or 933 patents.

100. On August 22, 2008, Penwest and Endo sued Sandoz in the United States District Court for the District of Delaware alleging infringement of the '456 patent only (but not the '250 or '933 patents), triggering the 30-month stay under the Hatch-Waxman Amendments.

101. On or about November 17, 2008, Sandoz sent another Paragraph IV Notice, informing Penwest and Endo that it had amended its ANDA to include 7.5 mg, 15 mg, and 30 mg strengths of generic Opana ER.

102. On or about December 30, 2008, Penwest and Endo filed a second suit against Sandoz in the United States District Court for the District of Delaware alleging infringement of the '456 patent (but not the '250 or '933 patents) for 7.5 mg, 15 mg, and 30 mg strengths of generic Opana ER, again triggering the 30-month stay under the Hatch-Waxman Amendments.

103. The two Sandoz suits were transferred to and consolidated in the United States District Court for the District of New Jersey under the lead docket number 09-836 (the "Sandoz Patent Litigation").

3. Barr Patent Infringement Suit

104. Between September 11 and 12, 2008, Barr sent Penwest and Endo Paragraph IV Notices with respect to Barr's generic Opana ER ANDA 90-106 asserting that Barr's generic 5 mg, 10 mg, 20 mg, and 40 mg tablets would not infringe the '250, '456 or '933 patents or the patents were invalid or not enforceable.

105. On October 20, 2008, Penwest and Endo sued Barr in the United States District Court for the District of Delaware alleging that Barr's ANDA product would infringe the '456 and '933 patents (but not the '250 patent), triggering the 30-month stay under the Hatch-Waxman Amendments.

106. On or about June 1, 2009, Penwest and Endo received another Paragraph IV Notice from Barr covering the 7.5 mg, 15 mg, and 30 mg strengths of generic Opana ER.

107. Shortly thereafter, on July 2, 2009, Penwest and Endo filed another suit against Barr in the United States District Court for the District of New Jersey alleging infringement of only the '456 and '933 patents (but not the '250 patent), again triggering the 30-month Hatch-Waxman stay for the 7.5 mg, 15 mg, and 30 mg strengths of Barr's generic Opana ER.

108. The two Barr suits were transferred to and consolidated in the United States District Court for the District of New Jersey under the lead docket number 09-838 (the "Barr Patent Litigation").

4. Roxane Patent Infringement Suit

109. On or about December 28, 2009, Roxane sent Penwest and Endo a Paragraph IV Notice with respect to Roxane's ANDA 20-0822 for generic Opana ER in a 40 mg dosage strength, explaining that the Roxane generic would not infringe the '250, '456 or '933 patents.

110. On or about January 29, 2010, Penwest and Endo filed a lawsuit against Roxane in the United States District Court for the District of New Jersey alleging infringement of only the '456 patent (but not '933 or '250 patents), triggering the 30-month stay under the Hatch-Waxman Amendments.

111. On or about March 18, 2010, Roxanne sent a second Paragraph IV Notice to Penwest and Endo (covering generic Opana ER in the 7.5 mg, 10 mg, 15 mg, 20 mg, and 30 mg strengths), again asserting that the Roxane generic products would not infringe the '250, '456 or '933 patents.

112. On or about April 16, 2010, Penwest and Endo again sued Roxanne, alleging infringement of the '456 patent (but not '933 or '250 patents), triggering the 30-month Hatch-Waxman stay.

113. The Roxane suits were later consolidated in the United States District Court for the District of New Jersey under the lead docket number 10-534 (the "Roxane Patent Litigation").

5. Watson Patent Infringement Suit

114. On or about January 19, 2010, Penwest and Endo received a Paragraph IV Notice from Watson advising that Watson's ANDA 20-0792 for generic Opana ER in a 40 mg dosage strength would not infringe the '250, '456 or '933 patents.

115. On or about March 4, 2010, Penwest and Endo sued Watson in the United States District Court for the District of New Jersey alleging infringement of the '456 and '933 patents (but not the '250 patent), triggering the 30-month stay under the Hatch-Waxman Amendments (the "Watson Patent Litigation").

116. On or about March 18, 2010, Watson sent additional Paragraph IV Notices regarding ANDA 20-0792 for the 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, and 30 mg dosage strengths.

117. On April 23, 2010, Penwest and Endo amended the Watson complaint to include infringement allegations regarding the additional dosage strengths and therefore triggered the 30-month Hatch-Waxman stay with regard to the 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, and 30 mg strengths as well.

E. Penwest, Endo, and Impax Enter the Exclusion Payment Agreements

1. Penwest, Endo, and Impax Settle the Impax Patent Litigation

118. From 2007 to 2010, during the 30-month stay period, Penwest, Endo, and Impax litigated their patent infringement suit in the United States District Court for the District of Delaware and then, following transfer and consolidation of the Impax patent cases, in the United States District Court for the District of New Jersey. The Impax Patent Litigation was

consolidated for pretrial purposes with the Sandoz Patent Litigation and the Barr Patent Litigation.

119. The case proceeded through discovery and claim construction briefing. Judge Katherine S. Hayden of the District of New Jersey conducted a *Markman* Hearing and entered an order on claim construction on March 30, 2010.

120. In the March 8, 2010 Final Pretrial Order, Impax asserted that it would prove that the '456 and '933 patents were invalid because they were: (1) anticipated by prior art; (2) obvious; and (3) constituted obvious-type double patenting. Further, Impax intended to prove that the '933 patent lacked an adequate written description. Finally, Impax contended that even if those patents were valid, its generic Opana ER did not infringe the '250, '456, and '933 patents.

121. As noted above, the 30-month stay on Impax's ANDA was set to expire on or around June 14, 2010.

122. On May 4, 2010, Impax held its first quarter 2010 earnings call. During that call, Impax's CEO and CFO indicated that Impax was expecting to receive tentative approval of its generic Opana ER ANDA 79-046 by May 23, 2010, and that Impax was preparing to launch generic Opana ER.[20]

123. On May 13, 2010, as Impax had correctly anticipated, the FDA tentatively approved Impax's ANDA for all dosage strengths of Opana ER; final approval of Impax's generic Opana ER had to wait for the expiration of the 30-month stay on June 14, 2010.

124. The next day, May 14, 2010, during a telephonic hearing to discuss Penwest and Endo's desire to file a preliminary injunction motion to extend the statutory stay of FDA

[20] http://seekingalpha.com/article/202894-impax-laboratories-inc-q1-2010-earnings-call-transcript?part=single

approval of Impax's proposed generic tablets, counsel for Endo represented that Endo had "indications" that Impax was "actually going down that road" of making and stockpiling generic Opana ER product (that is, Endo understood that Impax was preparing to make an at-risk launch). In response, counsel for Impax represented that Impax "certainly . . . will have the right to launch the [Opana ER generic] product upon final approval in mid-June."[21] Counsel for Impax also stated: "I certainly today could not say that we would agree not to launch on June 14th. It is our statutory right to launch the product after final approval."[22]

125. With the trial of the Impax and Sandoz Patent Litigations set to commence on June 3, 2010 and conclude by June 17, 2010, and to avoid distractions caused by briefing the preliminary injunction motion seeking to extend the statutory stay of FDA approval of Impax's proposed generic tablets filed by Endo, Impax agreed "not [to] launch its ANDA product (generic oxymorphone hydrochloride extended-release tablets) through and including the last trial day as presently scheduled" in a May 20, 2010 letter to Judge Hayden.[23]

126. The bench trial commenced on June 3, 2010, and continued through two days – June 3 and June 7, 2010.

127. Penwest and Endo were aware that their patents and patent infringement claims against Impax were weak and that they would not be able to obtain an injunction to stop Impax from launching its generic versions of Opana ER after Impax obtained final approval of its generic products from the FDA. Likewise, Impax knew the risk of an adverse decision at trial – regardless of how small the possibility – would jeopardize its 180-day marketing exclusivity of

[21] *Endo Pharmaceuticals Inc. v. Impax Laboratories Inc.*, 2:09-cv-00831, ECF No. 214, at 10:20-25 (D.N.J. May 17, 2010).

[22] *Id.* at 16:14-19.

[23] *Id.*, ECF No. 222.

generic Opana ER. It also knew that it could make as much or more money by agreeing not to compete with Endo than by actually launching its generic Opana ER product.

128. Had Impax launched generic versions of Opana ER upon receiving FDA final approval for its 5 mg, 10 mg, 20 mg, and 40 mg strengths on June 14, 2010 (representing the vast majority of Opana ER sales) or at the conclusion of the trial, as it was preparing and poised to do prior to entering the Exclusion Payment Agreements, Impax's generics would have driven down the price of extended release oxymorphone hydrochloride tablets. Impax was further aware that once its 180-day exclusivity period ran, there would be multiple generic versions of Opana ER available, accelerating the erosion of prices on both Opana ER and Impax's generic.

129. With the bench trial underway, rather than Penwest and Endo risk potentially losing its patent protection for Opana ER, Penwest and Endo settled the Impax Patent Litigation by contemporaneously entering into the Exclusion Payment Agreements on or about June 8, 2010. The bench trial transcripts were ordered sealed, and on June 15, 2010, the Impax Patent Litigation was dismissed with prejudice.

2. The Exclusion Payment Agreements Provide Impax With Over $100 Million to Keep Generic Versions of Opana ER off the Market

130. As part of its settlement with Impax, Endo granted Impax licenses to the patents covering Opana ER. In addition, Endo provided Impax a future cash payment of $102 million as well as other consideration. In exchange, Impax agreed to delay the launch of its generic Opana ER products until January 1, 2013.

131. The Exclusion Payment Agreements provided for a future cash payment of $102,049,000 from Endo to Impax if sales of Opana ER fell below a predetermined contractual threshold in the quarter immediately prior to January 1, 2013. Although styled as a "conditional" payment, it was anything but.

132. Endo had already planned on moving the prescription patterns away from Opana ER to a new crush-resistant formulation of Opana ER. This is borne out by the fact that on July 7, 2010, just one month after Endo ended its patent litigation with Impax, Endo filed NDA 201655 for the approval Opana ER CRF, a crush-resistant formulation of Opana ER. Endo had been planning this move for some time prior to settlement.

133. In December 2007, Endo entered into a License, Development and Supply Agreement with Grüenenthal GmbH "for the exclusive clinical development and commercialization rights in Canada and the United States for a new oral formulation of long-acting oxymorphone [Opana ER], which is designed to be crush resistant."[24] As part of this agreement, Endo was to receive a variety of licenses for patents developed by Grüenenthal that would cover Opana ER CRF, and potentially protect it from competition until at least 2023.[25]

134. On December 9, 2011, the FDA approved Endo's NDA for Opana ER CRF. In its letter of approval, the FDA stated that Endo's new crush resistant formulation was substantially similar as Opana ER, and that Endo's "support for the efficacy and safety of this new product was intended to be based entirely on bioequivalence to the previously approved product [Opana ER]."[26] Endo submitted no new safety, clinical efficacy, or nonclinical pharmacology/toxicology data in connection with its application – it only submitted a new blood sample analysis that confirmed the new formulation's bioequivalence to Opana ER. Thus, from the FDA's standpoint, Opana ER and Opana ER CRF are bioequivalent. Because Opana ER

[24] Endo 2010 Form 10-K, at 31.

[25] Susan Jeffrey, FDA Approves Tamper-Resistant Oxymorphone Formulation, MedScape Multispecialty (Dec. 12, 2011), http://www.medscape.com/viewarticle/755260 ("The company [Endo] also announced that the US Patent and Trademark Office will issue a patent on December 13, 2011, to cover the new formulation of Opana ER. This patent is expected to provide patent protection until November 2023. The new patent will be listed in the FDA's Orange Book, the statement notes.").

[26] FDA Division Director's Review and Summary Basis for Approval Action NDA 201655 – Opana ER (New Formulation), at 1 (Dec. 9, 2011).

CRF is bioequivalent to Opana ER, there is no additional or different therapeutic benefit over Opana ER, meaning that generic versions of Opana ER could be prescribed by healthcare professionals in lieu of Opana ER or Opana ER CRF.[27]

135. After receiving FDA approval, Endo launched Opana ER CRF in the beginning of 2012. At the same time, it launched a promotional campaign to convert all Opana ER prescriptions to Opana ER CRF. In doing this, Endo employed a two-pronged approach: First, Endo discontinued its marketing of Opana ER – starting with the 7.5 mg and 15 mg strengths of Opana ER in March 2011, and followed by the remaining strengths on May 31, 2012[28] – and began aggressively promoting of Opana ER CRF to healthcare providers.

136. Second, to ensure the success of its promotional efforts to switch healthcare providers to the crush resistant formulation of Opana ER, Endo filed a Citizen Petition[29] with the FDA in September 2012 to have the FDA withdraw marketing approval for Opana ER – as well as any ANDA seeking FDA approval of generic versions Opana ER – on the grounds that non-crush resistant versions of Opana ER were no longer safe to use. Specifically, the Citizen Petition asked the FDA to:

> Determine that the discontinued, non-crush resistant version of Opana ER approved under NDA No. 021610 was discontinued for reasons of safety and can no longer serve as an RLD [Reference Listed Drug] for an ANDA applicant;
>
> Refuse to approve any pending ANDA for a generic version of the non-crush-resistant version of Opana ER approved under NDA No. 021610; and

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[27] Although the FDA found that Opana ER CRF and Opana ER "have the same therapeutic benefits," Endo CP Final Decision at 8, to date the FDA has not formally determined that generic versions of Opana ER would be AB-rated generic equivalents of Opana ER CRF. Because generic versions of Opana ER are not given the "AB" designation with respect to Opana ER CRF, pharmacies are not permitted to automatically substitute generic versions of Opana ER with Opana ER CRF scripts.

[28] Endo CP Final Decision at 1.

[29] Under 21 U.S.C. § 355(q) and 21 C.F.R. § 10.30, a person may petition the FDA for specific administrative relief.

> Suspend and withdraw the approval of any ANDA referencing Opana ER approved under NDA No. 021610 as the RLD.[30]

137. Endo filed its Citizen Petition knowing that if it was successful, it would arrest any generic competition in the extended-release oxymorphone hydrochloride market because all existing ANDAs (whether previously approved or not) would be rejected, as they were all based on the safety and efficacy studies of the non-crush resistant formulation of Opana ER. As the date for Impax's launch drew nearer, Endo became so desperate to have the FDA act in its favor that it filed a lawsuit against the FDA seeking a final determination on Endo's Citizen Petition.[31] The United States District Court for the District of Columbia dismissed Endo's complaint at the request of the FDA.

138. Ultimately, in May 2013, the FDA rejected Endo's Citizen Petition, finding that Endo's discontinuation of Opana ER was not "for reasons of safety or effectiveness."[32] As a result, "ANDAs referencing NDA 21-610 may be approved as long as they meet all other legal and regulatory requirements for the approval of ANDAs, and will not begin procedures to suspend or withdraw approval of ANDAs that reference NDA 21-610."[33]

139. Impax anticipated (or in fact knew) of Endo's plans to move the market away from Opana ER to a crush resistant formulation of Opana ER. As a result, Impax negotiated for the provision of a $102 million "conditional" payment knowing that it was all but certain to be paid. From Impax's perspective, even if Endo's marketing efforts and Citizen Petition were successful in making Opana ER CRF the exclusive formulation of extended-release oxymorphone hydrochloride – thereby jeopardizing the marketing success of Impax's generic

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[30] Endo Citizen Petition, Docket No. FDA-2012-P-0895, at 1.

[31] *Endo Pharmaceuticals Inc. v. FDA*, 1:12-cv-01936 (D.D.C. Nov. 30, 2012).

[32] FDA Statement: Original Opana ER Relisting Determination (May 10, 2013), http://www.fda.gov/Drugs/DrugSafety/ucm351357.htm.

[33] Endo CP Final Decision at 1.

version of Opana ER during its 180-day exclusivity period – the bounty of its 180-day exclusivity period had already been obtained in part through the $102 million cash payment.

140. Endo was perfectly happy to oblige and pay that amount because it would: (1) preserve its monopoly over extended-release oxymorphone hydrochloride because Opana ER would be without a generic competitor until January 1, 2013; and (2) give Endo the time it needed to successfully move the market to its forthcoming crush resistant formulation of Opana ER.

141. Impax received the total $102 million payment in April 2013. In addition to the $102 million payment, the Exclusion Payment Agreements also included a development and co-promotion agreement where Endo agreed to pay Impax $10 million up-front with an obligation to pay $30 million in additional payments if certain milestones were met. The $30 million payments include:

- $15 million upon the achievement of clinical events;
- $5 million upon the achievement of regulatory events; and
- $10 million upon the achievement of commercialization events.

142. Publicly, Defendants stated that the development and co-promotion payments were for certain rights related to Impax's as-yet-unapproved next generation Parkinson's disease product.

143. To date, pursuant to the Exclusion Payment Agreements, Impax has received at least $112,049,000 in cash (a deferred payment of $102,049,000 explicitly compensating Impax for delaying entry plus an additional $10 million in cash up front as part of the purported Parkinson's drug agreement) in exchange for keeping Impax's generic Opana ER off the market for two and a half years.

144. Defendants have no pro-competitive explanation or justification for the payments. These large, unjustified payments had no rational connection to, and far exceeded, any approximation of the costs of continuing the patent litigation that was in the middle of trial at the time the agreement was signed. Nor was the payment consideration for the fair value of any pro-competitive services provided by Impax to Endo. Impax was not required to perform any service at all in exchange for the more than $102 million cash payment. Impax was also not required to perform any service for the $10 million upfront cash payment that was purportedly related to Impax's unapproved drug product. Endo simply paid Impax not to compete.

145. Absent Endo's unlawful payments to Impax under the Exclusion Payment Agreements, Endo and Impax would have settled in a manner less restrictive of competition, resulting in much less delay of Impax's generic entry than as happened pursuant to a settlement with unlawful payments. Under such an agreement, or even without one (such as with an at-risk launch by Impax, or after a ruling in Impax's favor), Impax would have launched its generic Opana ER substantially earlier than 2013.

3. Effects of the Exclusion Payment Agreements

146. The FDA granted final approval of Impax's ANDA for generic Opana ER tablets 5 mg, 10 mg, 20 mg, and 40 mg on June 14, 2010. A little over a month later, on July 22, 2010, the FDA granted final approval of Impax's ANDA for generic Opana ER tablets 30 mg.

147. The Exclusion Payment Agreements enabled Endo and Impax to (a) delay entry of less expensive generic versions of Opana ER 5 mg, 10 mg, 20 mg, 30 mg, and 40 mg strengths in the United States; (b) fix, raise, maintain or stabilize the price of 5 mg, 10 mg, 20 mg, 30 mg, and 40 mg strengths of Opana ER products, and its generic equivalents; (c) permit Endo to maintain a monopoly in the United States market for Opana ER and its generic

equivalents; and (d) allocate the market for Opana ER and its generic equivalents almost exclusively to Endo through January 2013.

148. The Exclusion Payment Agreements had the effect of delaying competition for 5 mg, 10 mg, 20 mg, 30 mg, and 40 mg extended-release oxymorphone hydrochloride tablets for two and a half years. But for the Exclusion Payment Agreements, Impax would have begun marketing and selling its generic Opana ER as early as June 14, 2010 for the 5 mg, 10 mg, 20 mg, and 40 mg strengths, and July 22, 2010 for the 30 mg strength, which as stated above are the dates when Impax obtained final FDA approval of these strengths of generic Opana ER.

149. Instead, as a result of the Exclusion Payment Agreements, Impax did not launch its 5 mg, 10 mg, 20 mg, 30 mg, and 40 mg of generic Opana ER tablets until January 4, 2013.

150. In addition, Endo and Impax, the first generic filer for the 5 mg, 10 mg, 20 mg, 30 mg, and 40 mg strengths of generic Opana ER tablets, also knew and intended that their Exclusion Payment Agreements would prevent other generic companies from launching their own generic products in those strengths.

151. As the first-filer of an ANDA with a Paragraph IV certification for generic Opana ER for 5 mg, 10 mg, 20 mg, 30 mg, and 40 mg strengths, Impax was entitled to market its generic Opana ER in those strengths for 180 days free from competition from other generic Opana ER tablets at those strengths. Indeed, Endo admitted this stating in its 2011 Form 10-K, that "[w]e expect Sandoz, Teva, Watson, Roxane and Actavis to launch production and sale of all strengths of their respective versions of generic non-tamper resistant Opana® ER commencing on July 1, 2013 [*i.e.*, 180 days after the Impax launch]."[34]

[34] Endo Pharmaceuticals Holdings Inc. 2011 Form 10-K, at F-75.

152. In other words, the Exclusive Payment Agreements with Impax created a bottleneck. So long as there was not a court ruling invalidating the '456 and '933 patents (which would trigger Impax's 180-day exclusivity period), Impax's delayed 180-day exclusivity period under the Exclusion Payment Agreements prevented any generic, other than Impax, from entering the market until July 2013.

153. Thus, Defendants' Exclusion Payment Agreements delayed or prevented the sale of generic Opana ER 5 mg, 10 mg, 20 mg, 30 mg, and 40 mg strengths in the United States for more than two and a half years, and unlawfully enabled Endo to sell branded Opana ER 5 mg, 10 mg, 20 mg, 30 mg, and 40 mg strengths at supracompetitive prices.

154. But for Defendants' illegal Exclusion Payment Agreements, generic competition to Opana ER 5 mg, 10 mg, 20 mg, 30 mg, and 40 mg strengths would have occurred as early as June 14, 2010, when Impax received final approval for its ANDA in the 5 mg, 10 mg, 20 mg, and 40 mg dosage strengths and July 22, 2010 for the 30 mg dosage strength. Further, if Impax had launched in June 2010, the market for Opana ER would not have been substantially eroded by the switch to Opana ER CRF, and Impax would have made far more sales. Moreover, the Exclusion Payment Agreements blocked one or more generic manufacturers from launching generic versions Opana ER in or around December 2010, when Impax's 180-day exclusivity period would have expired absent the Exclusion Payment Agreements.

F. Endo Settles the Actavis, Barr, Sandoz, Watson, and Roxane Patent Litigations

1. Endo Ends Its Patent Litigation Against Actavis

155. Less than a year after suing Actavis, on or about February 20, 2009, Endo settled all of the Actavis Patent Litigation (the "Actavis Settlement"). On February 25, 2009, the Actavis Patent Litigation was dismissed with prejudice.

156. As discussed above, Actavis was the first-filer on the 7.5 mg and 15 mg strengths of generic Opana ER. At all relevant times, these two strengths have never constituted more than 10% of Endo's Opana ER sales.

157. Under the terms of the Actavis Settlement, Actavis agreed not to challenge the validity or enforceability of the '250, '456, and '933 patents and Endo agreed to grant Actavis a license permitting the production and sale of generic Opana ER 7.5 mg and 15 mg tablets by the earlier of July 15, 2011, or the date on which any third party commences commercial sales of a generic oxymorphone hydrochloride extended-release tablets, but not before November 28, 2010.

158. Endo also granted Actavis a license to produce and market other strengths of generic Opana ER on the earlier of July 15, 2011 or the date on which any third party commences commercial sales of a generic form of the drug. However, Endo's Exclusion Payment Agreements with Impax rendered that portion of the agreement with Actavis illusory as Endo and Impax used Impax's first-filer status to prevent any other generics from launching those strengths earlier than July 2013 (180 days after Impax's January 2013 launch).

159. Indeed, the FDA in its December 13, 2010 letter granting final approval to Actavis's 7.5 mg and 15 mg strengths of generic extended-release oxymorphone hydrochloride confirmed that Actavis would not be able to launch its generic Opana ER for the remaining strengths as arranged in its settlement with Endo, stating:

> Your Oxymorphone Hydrochloride Extended-release Tablets, 5 mg, 10 mg, 20 mg, 30 mg, and 40 mg, are **tentatively approved**. . . . .
>
> We are unable to grant final approval to your Oxymorphone Hydrochloride Extended-release Tablets 5 mg, 10 mg, 20 mg, 30 mg, and 40 mg, at this time *because prior to the submission of your ANDA, another applicant submitted an ANDA providing for Oxymorphone Hydrochloride Extended-release Tablets 5 mg, 10 mg, 20 mg, 30 mg, and 40 mg, and containing a paragraph IV certification to the '933, '456, and*

> *'250 patents*. Your ANDA insofar as these strengths will be eligible for final approval on the date that is 180 days after the agency receives notice, with respect to the other ANDA, of the commercial marketing date identified in section 505(j)(5)(B)(iv) of the [FDCA].[35]

160. The "other applicant" referred to in the FDA's letter was Impax.

161. But for the Exclusion Payment Agreements between Endo and Impax, Actavis would have been able to launch its generic versions of the 5 mg, 10 mg, 20 mg, 30 mg, and 40 mg strengths of Opana ER 180 days following Impax's launch of those strengths in June 2010 and July 2010. However, due to the Exclusion Payment Agreement, Actavis did not launch those strengths until September 2013.

2. Endo Ends Its Patent Litigations Against Barr, Sandoz, Watson, and Roxane

162. On or about April 12, 2010, Endo settled all of the Barr Patent Litigation relating to Opana ER. Under the terms of the settlement, Endo agreed to grant Barr a license permitting the production and sale of all strengths of generic Opana ER commencing on September 15, 2012, or earlier under certain circumstances. This launch date was destined to be unrealized in light of the bottleneck formed by Endo and Impax in the Exclusion Payment Agreements because Barr could not launch its generic until 180 days after Impax launched in January 2013.

163. The Sandoz litigation had proceeded to a bench trial that was begun on June 3, 2010, before the Honorable Katherine S. Hayden of the United States District Court for the District of New Jersey. On or about June 8, 2010 (the same time as the Endo-Impax Exclusion Payment Agreements and prior to Judge Hayden issuing any dispositive rulings in the bench trial), Endo settled the Sandoz Patent Litigation relating to Opana ER. Under the terms of the settlement, Sandoz agreed not to challenge the validity or enforceability of the Opana ER Patents and Endo agreed to grant Sandoz a license permitting the production and sale of all strengths of

[35] FDA Letter to Actavis, at 5 (Dec. 13, 2010) (bold in original, italics added).

generic Opana ER commencing on September 15, 2012, or earlier under certain circumstances. This launch date was destined to be unrealized in light of the bottleneck formed by Endo and Impax in the Exclusion Payment Agreements because Sandoz could not launch its generic until 180 days after Impax launched in January 2013.

164. On or about October 7, 2010, Endo settled all of the Watson Patent Litigation relating to Opana ER. Under the terms of the settlement, Endo agreed to grant Watson a license permitting the production and sale of all strengths of generic Opana ER commencing on September 15, 2012, or earlier under certain circumstances. This launch date was destined to be unrealized in light of the bottleneck formed by Endo and Impax in the Exclusion Payment Agreements because Watson could not launch its generic until 180 days after Impax launched in January 2013.

165. On or about May 4, 2011, Endo settled all of the Roxane Patent Litigation relating to Opana ER. Under the terms of the settlement, Endo agreed to grant Roxane a license permitting the production and sale of all strengths of generic Opana ER commencing on September 15, 2012, or earlier under certain circumstances. This launch date was destined to be unrealized in light of the bottleneck formed by Endo and Impax in the Exclusion Payment Agreements because Roxane could not launch its generic until 180 days after Impax launched in January 2013.

166. Notwithstanding agreements for nominal entry dates in 2012, Barr, Sandoz, Watson, and Roxane were not able to sell their generic Opana ER products until 180 days after Impax's generic launch. As such, the real launch date for Barr, Sandoz, Watson, and Roxane generics could not be before July 2013, a delay that Endo secured through Endo's Exclusion Payment Agreements with Impax.

167. The importance of the Barr, Sandoz, Watson, and Roxane settlements for Endo was that they prevented a court ruling that could threaten the validity of the '250, '456 and '933 patents and move up the trigger date for Impax's 180-day exclusivity period and the launch of generic Opana ER.

MARKET CHARACTERISTICS

168. At all relevant times, Endo has had monopoly power over the market for extended-release oxymorphone hydrochloride oral tablets, as evidenced by its ability to maintain the price of Opana ER at monopolistic levels without losing substantial sales to other products.

169. Opana ER does not exhibit significant, positive cross-elasticity of demand with respect to price with any product other than an AB-rated generic equivalent of Opana ER.

170. Because of its unique profile as an extended-release oxymorphone hydrochloride oral tablet, Opana ER is differentiated from all products other than AB-rated generic equivalents of Opana ER.

171. Endo needed to control only Opana ER (and any AB-rated generic equivalent to Opana ER)—and no other products—to maintain the price of Opana ER profitably at monopolistic prices. Only the market entry of a competing AB-rated generic equivalent to Opana ER would render Endo unable to profitably maintain monopolistic prices of Opana ER without losing substantial sales.

172. Endo also sold Opana ER at prices well in excess of marginal costs and the competitive price, and enjoyed high profit margins.

173. Endo exercised the power to exclude generic competition to Opana ER.

174. At all relevant times, Endo enjoyed high barriers to entry with respect to the market for extended-release oxymorphone hydrochloride oral tablets.

175. To the extent that Plaintiff is legally required to define a relevant product market, Plaintiff alleges that the relevant market is all extended-release oxymorphone hydrochloride products, which includes Opana ER and AB-rated bioequivalent products. During the relevant time period, Endo has been able to profitably maintain the price of Opana ER well above competitive levels.

176. The relevant geographic market is the United States and its territories.

177. At all relevant times, Endo has had a 100% market share in the relevant market.

MARKET EFFECTS

178. Endo began marketing Opana ER in or around December 2006.

179. Defendants' anticompetitive scheme had the purpose and effect of unreasonably restraining and injuring competition by protecting Opana ER from generic competition. But for Exclusion Payment Agreements, Impax would have entered the market upon receiving final FDA approval or agreed to an unrestrained licensed entry date much earlier than January 1, 2013.

180. But for Defendants' illegal conduct, generic competition would have forced a decrease in the price of Opana ER, and price competition among the suppliers of branded and generic Opana ER would have been intense.

181. But for Defendants' illegal conduct, Plaintiff and Class Members would have paid less for Opana ER or a generic equivalent. Defendants' conduct directly injured Plaintiff and Class Members because it forced them to pay hundreds of millions of dollars in overcharges on their Opana ER purchases.

182. As a result of the delay in generic competition brought about by Defendants' anticompetitive scheme, Plaintiff and Class Members paid more for Opana ER products than they would have paid absent Defendants' illegal conduct.

183. Impax had extensive experience in the pharmaceutical industry, including experience obtaining approval of ANDAs, manufacturing commercial launch quantities adequate to meet market demand, and marketing generic pharmaceutical products.

184. Upon entering the market, generic equivalents of brand name drugs are priced below the branded drug to which they are AB-rated. When multiple generic products are on the market, prices for the brand drug and its generic equivalents fall even further because of the increased competition.

185. If generic competition for Opana ER had not been unlawfully delayed, Plaintiff and Class Members would have paid less for Opana ER by (a) substituting purchases of less-expensive AB-rated generic equivalents of Opana ER for their purchases of more-expensive brand Opana ER, and (b) purchasing Opana ER at a reduced price.

186. Thus, Defendants' unlawful conduct deprived Plaintiff and Class Members of the benefits of competition that the antitrust laws were designed to ensure.

ANTITRUST IMPACT

187. During the relevant period, Plaintiff and Class Members purchased substantial amounts of Opana ER indirectly from Endo. As a result of the Defendants' illegal conduct, these purchasers were compelled to pay artificially inflated prices for Opana ER. Those prices were substantially higher than the prices that Plaintiff and Class Members would have paid absent the illegal conduct alleged in this Complaint.

188. As a consequence, purchasers of Opana ER have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount, forms, and components of such damages will be calculated after discovery and upon proof at trial.

189. Defendants' efforts to restrain competition in the market for Opana ER have substantially affected interstate commerce.

190. At all material times, Endo manufactured, promoted, distributed, and sold substantial amounts of Opana ER in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States. Defendants' anticompetitive conduct had substantial intrastate effects in every state of purchase in that, among other things, retailers within each state were foreclosed from offering cheaper generic equivalents of Opana ER to purchasers within each state, which directly impacted and disrupted commerce for consumers and third-party payors within each state.

191. At all material times, Defendants transmitted funds and contracts, invoices, and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Opana ER.

192. General economic theory recognizes that any overcharge at a higher level of distribution generally results in higher prices at every level below. Professor Herbert Hovenkamp explains that "[e]very person at every stage in the chain will be poorer" as a result of the anticompetitive price at the top. [36] He also says that "[t]heoretically, one can calculate the percentage of any overcharge that a firm at one distribution level will pass on to those at the next level."[37]

193. The institutional structure of pricing and regulation in the pharmaceutical drug industry ensures that overcharges at the higher level of distribution are passed on to end-payors. Wholesalers and retailers passed on the inflated prices of Opana ER to Plaintiff and Class Members.

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[36] *See* Herbert Hovenkamp, *Federal Antitrust Policy: The Law of Competition and Its Practice*, at 564 (1994).

[37] *Id.*

194. Defendants' anticompetitive conduct enabled Endo to indirectly charge consumers and third-party payors prices in excess of what they otherwise would have been able to charge absent the Defendants' unlawful actions.

195. The prices were inflated as a direct and foreseeable result of Defendants' anticompetitive conduct.

196. The inflated prices that Plaintiff and Class Members have paid are traceable to, and the foreseeable result of, the overcharges by Endo.

CLASS ACTION ALLEGATIONS

197. Plaintiff brings this action as a class action, under Fed. R. Civ. P. 23(a), (b)(2), and (b)(3), on behalf of itself and the following similarly situated individuals:

> All persons or entities in the United States and its territories who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for Opana ER 5 mg, 10 mg, 20 mg, 30 mg and 40 mg tablets and/or its AB-rated generic equivalents in any form, other than for resale, for consumption by itself, its families, or its members, employees, insureds, participants, or beneficiaries (the "Class"), from June 14, 2010 through and including the date that the anticompetitive effects of Defendants' unlawful conduct cease (the "Class Period").

198. The following persons and entities are excluded from each of the above-described proposed Classes:

(a) Defendants and their counsel, officers, directors, management, employees, subsidiaries, or affiliates;

(b) All governmental entities, except for government-funded employee benefit plans;

(c) All persons or entities who purchased Opana ER for purposes of resale or directly from Defendants or their affiliates;

(d) Fully-insured health plans (plans that purchased insurance from another third-party payor covering 100% of the plan's reimbursement obligations to its members);

(e) Flat co-payers (consumers who paid the same co-payment amount for brand and generic drugs); and

(f) The judges in this case and any members of their immediate families.

199. The Class Members are so numerous that joinder is impracticable. Plaintiff believes that there are thousands of Class Members.

200. Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff and Class Members were damaged by the same wrongful conduct by Defendants in that they paid artificially inflated prices for Opana ER and were deprived of the benefits of earlier and more robust competition from cheaper generic equivalents of Opana ER as a result of Defendants' wrongful conduct.

201. Plaintiff will fairly and adequately protect and represent the interests of the Class. Plaintiff's interests are coincident with, and not antagonistic to, those of the Class Members.

202. Plaintiff is represented by counsel with experience in the prosecution of class action antitrust litigation, and with experience in class action antitrust litigation involving pharmaceutical products.

203. Questions of law and fact common to the Class Members predominate over questions that may affect only individual Class Members because Defendants have acted on grounds generally applicable to the entire Class, making overcharge damages with respect to the Class as a whole appropriate.

204. Questions of law and fact common to all class members include:

(a) whether Defendants conspired to restrain generic competition to Opana ER;

(b) whether Impax unlawfully agreed to delay its entry into the market for extended release oxymorphone hydrochloride tablets, *i.e.*, Opana ER and its AB-rated generic bioequivalents;

(c) whether Endo paid Impax in exchange for a delay in generic competition for Opana ER;

(d) whether Defendants' conduct suppressed generic competition to Opana ER;

(e) whether Defendants' conduct harmed competition in the market for extended release oxymorphone hydrochloride, *i.e.*, Opana ER and its AB-rated generic bioequivalents;

(f) whether Endo possessed market power in the market for extended-release oxymorphone hydrochloride, *i.e.*, Opana ER and its AB-rated generic bioequivalents;

(g) whether the relevant antitrust market (if a relevant market must be defined) is the market for extended-release oxymorphone hydrochloride, *i.e.*, Opana ER and its AB-rated generic bioequivalents;

(h) whether Defendants' activities alleged herein have substantially affected interstate and intrastate commerce;

(i) whether, and to what extent, Defendants' conduct caused antitrust injury to the business or property of Plaintiff and members of the Class in the nature of overcharges; and

(j) the quantum of overcharges paid by Plaintiff and the Class in the aggregate.

205. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated, geographically dispersed persons or entities to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs any potential difficulties in management of this class action.

206. Plaintiff knows of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

FRAUDULENT CONCEALMENT TOLLED THE STATUTE OF LIMITATIONS

207. Plaintiff and Class Members had no knowledge of the Defendants' unlawful self-concealing scheme and could not have discovered the scheme and conspiracy through the exercise of reasonable diligence more than four years prior to the filing of this Complaint.

208. This is true because the nature of Defendants' conspiracy was self-concealing and Defendants employed deceptive practices and techniques of secrecy to avoid detection of, and to fraudulently conceal, their contract, combination, conspiracy, and scheme. Notwithstanding the self-concealing nature of their conspiracy, Defendants and their co-conspirators wrongfully and affirmatively concealed the existence of their continuing combination and conspiracy from Plaintiff and class members by, among other things:

(a) Concealing the amounts that Endo was to pay and paid Impax under the Exclusion Payment Agreements—particularly the $102 million payment,

which to Plaintiff's best knowledge, was not revealed prior to Endo's First Quarter 10-Q in 2012;

(b) Concealing the fact that the purpose of the payments under the Exclusion Payment Agreements was to provide compensation to Impax in connection with the settlement of the Impax Patent Litigation and to delay the entry date for Impax's generic product; and

(c) Concealing the fact that those amounts far exceeded any lawful economic benefit that Endo received from Impax under the Exclusion Payment Agreements.

209. Because the alleged conspiracy was both self-concealing and affirmatively concealed by Defendants and their co-conspirators, Plaintiff and Class Members had no knowledge of the conspiracy more than four years prior to the filing of this Complaint, or of the facts or information that would have caused a reasonably diligent person to investigate whether a conspiracy existed.

210. Plaintiff and Class Members also lacked the facts and information necessary to form a good faith basis for believing that any legal violations had occurred, including the amounts of payments made from Endo to Impax under the Exclusion Payment Agreements. Reasonable diligence on the part of Plaintiff and Class Members would not have uncovered those facts more than four years prior to the filing of this Complaint.

211. As a result of Defendants' fraudulent concealment, all applicable statutes of limitations affecting Plaintiff and Class Members' claims have been tolled.

212. Alternatively, if the statute of limitations is not tolled, Plaintiff alleges a continuing course of conduct (including conduct within the limitations period), and Plaintiff and Class Members can recover damages they suffered during the limitations period.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

Violation of Sherman Act § 1, 15 U.S.C. § 1 (Against All Defendants)

213. Plaintiff incorporates the preceding paragraphs by reference.

214. Defendants knowingly, intentionally, and cooperatively engaged in an anticompetitive scheme designed to delay and block entry of AB-rated generic equivalents of Opana ER. The intended and accomplished goal of the scheme was to use restrictive and exclusionary conduct to delay Impax's launch date for the first generic equivalent of Opana ER. Defendants injured Plaintiff and Class Members through an agreement to exclude generic Opana ER products from the market in exchange for substantial payments to Impax.

215. Had manufacturers of generic Opana ER products entered the market and lawfully competed with Endo in a timely fashion, Plaintiff and Class Members would have substituted lower-priced generic Opana ER products for the higher-priced brand name Opana ER for some or all of their purchases, and would have paid lower net prices on their remaining Opana ER purchases.

216. Defendants intended, and accomplished, a horizontal market allocation of the Opana ER market, which is a per se violation of Section 1 of the Sherman Act. By their agreement, the Defendants intentionally and wrongfully conspired and combined in an unreasonable restraint of trade in violation of Section 1 of the Sherman Act. As a result of this

unreasonable restraint on competition, Plaintiff and Class Members paid artificially inflated prices for Opana ER.

217. Plaintiff and Class Members have suffered harm, and will continue to suffer harm in the future, as a result of paying higher prices for Opana ER than they would have absent Defendants' anticompetitive conduct and continuing anticompetitive agreements. Plaintiff and Class Members also face a continuing threat of injury from the unlawful conduct alleged in this Complaint.

218. Plaintiff and Class Members have purchased substantial amounts of Opana ER indirectly from Endo.

219. Plaintiff and Class Members seek a declaratory judgment pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201(a) that the Defendants' conduct violates Section 1 of the Sherman Act.

220. Plaintiff and the Class also seek equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to correct for the anticompetitive market effects caused by Defendants' unlawful conduct, and other relief to ensure that similar anticompetitive conduct does not reoccur in the future.

SECOND CLAIM FOR RELIEF

Conspiracy and Combination in Restraint of Trade Under State Law (Against All Defendants)

221. Plaintiff incorporates the preceding paragraphs by reference.

222. Endo, Penwest, and Impax entered into Exclusion Payment Agreements to suppress generic competition for Opana ER. The Exclusion Payment Agreements involved the conduct set forth above. The Exclusion Payment Agreements are and were contracts,

combinations, and/or conspiracies that substantially, unreasonably, and unduly restrained trade in the relevant market, the purpose and effect of which to:

(a) Allocate close to 100% of the market for Opana ER in the United States to Endo;

(b) Prevent the sale of generic versions of Opana ER in the United States, thereby nearly completely protecting Opana ER from generic competition for at least two and one-half years during which time Endo could switch the market for Opana ER to Opana ER CRF;

(c) fix, raise, maintain or stabilize the price at which Plaintiff and Class Members would pay for Opana ER or its AB-rated generic equivalent at supracompetitive levels; and

(d) allocate close to 100% of United States generic Opana ER sales to Impax during the first 180 days of generic sales.

223. The Exclusion Payment Agreements harmed Plaintiff and the Class as set forth above.

224. The Exclusion Payment Agreements covered a sufficiently substantial percentage of the relevant market to harm competition.

225. The Exclusion Payment Agreements are horizontal market allocation and price fixing agreements between actual and potential competitors and are illegal per se under state antitrust laws. Alternatively, Plaintiff alleges that the Exclusion Payment Agreements are an unreasonable restraint of trade, in violation of state antitrust law, under a "quick look" or "rule of reason" analysis.

226. The Exclusion Payment Agreements between Endo and Impax regarding Opana ER involve (i) large and unjustified payments from Endo to Impax ($102 million and other consideration), and (ii) an agreement by Impax to delay marketing its generic Opana ER. Absent the Exclusion Payment Agreements, Impax would not have agreed to delay marketing its generic Opana ER and would have entered the market sooner than it did.

227. There is and was no legitimate, non-pretextual, procompetitive business justification for the payments that outweighs their harmful effect. Even if there were some such conceivable justification, the payments were not necessary to achieve such a purpose.

228. Defendants' conduct violated the following state antitrust laws:

(a) Ariz. Rev. Stat. §§ 44-1401, *et seq.*, with respect to purchases in Arizona by members of the Class;

(b) Cal. Bus. Code §§ 16700, *et seq.*, and Cal. Bus. Code §§ 17200, *et seq.*, with respect to purchases in California by members of the Class;

(c) D.C. Code Ann. §§ 28-4501, *et seq.*, with respect to purchases in the District of Columbia by members of the Class;

(d) Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases in Florida by members of the Class;

(e) Hawaii Code § 480, *et seq.*, with respect to purchases in Hawaii by members of the Class;

(f) Iowa Code §§ 553 *et seq.*, with respect to purchases in Iowa by members of the Class;

(g) Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases in Kansas by members of the Class;

(h) Mass. Gen. L. Ch. 93A, *et seq.*, with respect to purchases in Massachusetts by members of the Class;

(i) Me. Rev. Stat. Ann. 10, §§ 1101, *et seq.*, with respect to purchases in Maine by members of the Class;

(j) Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases in Michigan by members of the Class;

(k) Minn. Stat. §§ 325D.49, *et seq.*, with respect to purchases in Minnesota by members of the Class;

(l) Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to purchases in Mississippi by members of the Class;

(m) Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases in Nebraska by members of the Class;

(n) Nev. Rev. Stat. Ann. §§ 598A, *et seq.*, with respect to purchases in Nevada by members of the Class;

(o) N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases in New Mexico by members of the Class;

(p) N.Y. Gen. Bus. L. §§ 340, *et seq.*, with respect to purchases in New York by members of the Class;

(q) N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases in North Carolina by members of the Class;

(r) N.D. Cent. Code §§ 51-08.1-01, *et seq.*, with respect to purchases in North Dakota by members of the Class;

(s) 10 L.P.R.A. §§ 258, *et seq.*, with respect to purchases in Puerto Rico by members of the Class;

(t) R.I. Gen. Laws §§ 6-36-1 *et seq.*, with respect to purchases in Rhode Island by members of the Class;

(u) S.D. Codified Laws Ann. §§ 37-1, *et seq.*, with respect to purchases in South Dakota by members of the Class;

(v) Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases in Tennessee by members of the Class;

(w) Utah Code Ann. §§ 76-10-3101, *et seq.*, with respect to purchases in Utah by members of the Class;

(x) Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases in Vermont by members of the Class;

(y) W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases in West Virginia by members of the Class; and

(z) Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases in Wisconsin by members of the Class.

229. Plaintiff and Class Members have been injured in their business or property by Defendants' antitrust violations. Their injuries consist of (1) being denied the opportunity to purchase lower-priced generic Opana ER, and (2) paying higher prices for Opana ER products than they would have paid in the absence of Defendants' wrongful conduct. These injuries are of the type the above antitrust laws were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

230. Plaintiff and Class Members seek damages and multiple damages as permitted by law for the injuries they suffered as a result of Defendants' anticompetitive conduct.

231. Defendants are jointly and severally liable for all damages suffered by Plaintiff and Class Members.

232. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of the above-listed state antitrust laws.

THIRD CLAIM FOR RELIEF

Monopolization and Monopolistic Scheme Under State Law (Against Endo)

233. Plaintiff incorporates the preceding paragraphs by reference.

234. In June 2010, Endo, Penwest, and Impax entered into the Exclusion Payment Agreements to suppress generic competition with Opana ER. In November 2010, Endo acquired Penwest for $144 million. The Exclusion Payment Agreements had the effect of unlawfully maintaining Endo's monopoly over Opana ER by preventing Impax from launching competing generic versions of Opana ER until January 1, 2013.

235. Endo needed to control only Opana ER (and any AB-rated generic equivalent to Opana ER), and no other products, to maintain the price of Opana ER profitably at monopolistic prices. Only the market entry of a competing AB-rated generic equivalent to Opana ER would render Endo unable to profitably maintain monopolistic prices of Opana ER without losing substantial sales. The Exclusion Payment Agreements enabled Endo to maintain its monopoly and monopolistic prices over Opana ER.

236. Endo's conduct violated the following state antitrust laws::

(a) Ariz. Rev. Stat. §§ 44-1401, *et seq.*, with respect to purchases in Arizona by members of the Class;

(b) Cal. Bus. Code §§ 16700, *et seq.*, and Cal. Bus. Code §§ 17200, *et seq.*, with respect to purchases in California by members of the Class;

(c) D.C. Code Ann. §§ 28-4501, *et seq.*, with respect to purchases in the District of Columbia by members of the Class;

(d) Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases in Florida by members of the Class;

(e) Hawaii Code § 480, *et seq.*, with respect to purchases in Hawaii by members of the Class;

(f) Iowa Code §§ 553 *et seq.*, with respect to purchases in Iowa by members of the Class;

(g) Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases in Kansas by members of the Class;

(h) Mass. Gen. L. Ch. 93A, *et seq.*, with respect to purchases in Massachusetts by members of the Class;

(i) Me. Rev. Stat. Ann. 10, §§ 1101, *et seq.*, with respect to purchases in Maine by members of the Class;

(j) Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases in Michigan by members of the Class;

(k) Minn. Stat. §§ 325D.49, *et seq.*, with respect to purchases in Minnesota by members of the Class;

(l) Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to purchases in Mississippi by members of the Class;

(m) Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases in Nebraska by members of the Class;

(n) Nev. Rev. Stat. Ann. §§ 598A, *et seq.*, with respect to purchases in Nevada by members of the Class;

(o) N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases in New Mexico by members of the Class;

(p) N.Y. Gen. Bus. L. §§ 340, *et seq.*, with respect to purchases in New York by members of the Class;

(q) N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases in North Carolina by members of the Class;

(r) N.D. Cent. Code §§ 51-08.1-01, *et seq.*, with respect to purchases in North Dakota by members of the Class;

(s) 10 L.P.R.A. §§ 258, *et seq.*, with respect to purchases in Puerto Rico by members of the Class;

(t) R.I. Gen. Laws §§ 6-36-1 *et seq.*, with respect to purchases in Rhode Island by members of the Class;

(u) S.D. Codified Laws Ann. §§ 37-1, *et seq.*, with respect to purchases in South Dakota by members of the Class;

(v) Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases in Tennessee by members of the Class;

(w) Utah Code Ann. §§ 76-10-3101, *et seq.*, with respect to purchases in Utah by members of the Class;

(x) Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases in Vermont by members of the Class;

(y) W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases in West Virginia by members of the Class; and

(z) Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases in Wisconsin by members of the Class.

237. Plaintiff and Class Members have been injured in their business or property by Endo's antitrust violation. Their injuries consist of (1) being denied the opportunity to purchase lower-priced generic Opana ER, and (2) paying higher prices for Opana ER products than they would have paid in the absence of Endo's wrongful conduct. These injuries are of the type the above antitrust laws were designed to prevent, and flow from that which makes Endo's conduct unlawful.

238. Plaintiff and Class Members seek damages and multiple damages as permitted by law for the injuries they suffered as a result of Endo's anticompetitive conduct.

FOURTH CLAIM FOR RELIEF

Attempted Monopolization Under State Law (Against Endo)

239. Plaintiff incorporates the preceding paragraphs by reference.

240. Through the Exclusion Payment Agreements and related conduct, Endo specifically intended to maintain monopoly power in the relevant market. It was Endo's conscious objective to control prices and/or to exclude competition in the relevant market.

241. The natural and probable consequence of Endo's anticompetitive conduct, which was intended by it, and plainly foreseeable to them, was to control prices and exclude competition in the relevant market.

242. There was a substantial and real chance, a reasonable likelihood, and/or a dangerous probability that Endo would succeed in and achieve their goal of maintaining monopoly power in the relevant market.

243. As a direct and proximate result of Endo's illegal and monopolistic conduct, Plaintiff and the Class were harmed.

244. Endo defendants intentionally and wrongfully attempted to monopolize the market for extended-release oxymorphone hydrochloride in violation of the following state laws:

(a) Arizona Rev. Stat. §§ 44-1403, *et seq.*, with respect to purchases of Opana ER in Arizona by members of the Class.

(b) Cal. Bus. & Prof Code §§ 17200, *et seq.*, and California common law with respect to purchases of Opana ER in California by members of the Class.

(c) D.C. Code §§ 28-4503, *et seq.*, with respect to purchases of Opana ER in the District of Columbia by members of the Class.

(d) Fla. Stat. §§ 542.15, *et seq.* and §§ 501.201, *et seq.*, with respect to purchases of Opana ER in Florida by members of the Class.

(e) Hawaii Code §480, *et seq.*, with respect to purchases of Opana ER in Hawaii by members of the Class.

(f) 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases of Opana ER in Illinois by members of the Class.

(g) Iowa Code §§ 553.5 *et seq.*, with respect to purchases of Opana ER in Iowa by members of the Class.

(h) Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to purchases of Opana ER in Maine by members of the Class.

(i) Mich. Comp. Laws Ann. §§ 445.773, *et seq.*, with respect to purchases of Opana ER in Michigan by members of the Class.

(j) Minn. Stat. §§ 325D.49, *et seq.*, and Minn. Stat. § 8.31, with respect to purchases of Opana ER in Minnesota by members of the Class.

(k) Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of Opana ER in Mississippi by members of the Class.

(l) Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases of Opana ER in Nebraska by members of the Class.

(m) Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of Opana ER in Nevada by members of the Class.

(n) N.H. Rev. Stat. Ann. §§ 356.11, *et seq.*, with respect to purchases of Opana ER in New Hampshire by members of the Class.

(o) N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases of Opana ER in New Mexico by members of the Class.

(p) N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of Opana ER in North Carolina by members of the Class.

(q) N.D. Cent. Code §§ 51-08.1-03, *et seq.*, with respect to purchases of Opana ER in North Dakota by members of the Class.

(r) Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases of Opana ER in Oregon by members of the Class.

(s) 10 L.P.R.A. §§ 260, *et seq.*, with respect to purchases of Opana ER in Puerto Rico by members of the Class.

(t) R.I. Gen. Laws §§ 6-36-5 *et seq.*, with respect to purchases of Opana ER in Rhode Island by members of the Class.

(u) S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to purchases of Opana ER in South Dakota by members of the Class.

(v) Tenn. Code Ann §§ 47-25-101, *et seq.*, with respect to purchases of Opana ER in Tennessee by members of the Class.

(w) Utah Code Ann. §§ 76-10-911, *et seq.*, with respect to purchases of Opana ER in Utah by members of the Class who reside in Utah.

(x) Vt. Stat. Ann. tit. 9, §§ 2453, *et seq.*, with respect to purchases of Opana ER in Vermont by members of the Class.

(y) W.Va. Code §§ 47-18-4, *et seq.*, with respect to purchases of Opana ER in West Virginia by members of the Class.

(z) Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of Opana ER in Wisconsin by members of the Class.

245. Plaintiff and Class Members have been injured in their business or property by Endo's antitrust violation. Their injuries consist of (1) being denied the opportunity to purchase lower-priced generic Opana ER, and (2) paying higher prices for Opana ER products than they would have paid in the absence of Endo's wrongful conduct. These injuries are of the type the above antitrust laws were designed to prevent, and flow from that which makes Endo's conduct unlawful.

246. Plaintiff and Class Members seek damages and multiple damages as permitted by law for the injuries they suffered as a result of Endo's anticompetitive conduct.

FIFTH CLAIM FOR RELIEF

State Consumer Protection Violations
(Against All Defendants)

247. Plaintiff incorporates the preceding paragraphs by reference.

248. Defendants engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Defendants' anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiff and Class members were deprived of the opportunity to purchase a generic equivalent of Opana ER and forced to pay higher prices for their Opana ER requirements.

249. For years, there was a gross disparity between the price that Plaintiff and the Class members paid for the brand product when compared to the less expensive generic products, which should have been available.

250. By engaging in the foregoing conduct, Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of the following state unfair and deceptive trade practices and consumer protection statutes:

(a) Defendants have engaged in unfair or unconscionable acts or practices in violation of Ariz. Rev. Stat. §§ 44-1522, *et seq.*

(b) Defendants have engaged in unfair or unconscionable acts or practices in violation of Cal. Bus. & Prof. Code §§ 17200, *et seq.*

(c) Defendants have engaged in unfair or unconscionable acts or practices or made false representations in violation of D.C. Code §§ 28-3901, *et seq.*

(d) Defendants have engaged in unfair or unconscionable acts or practices in violation of Fla. Stat. §§ 501.201, *et seq.*

(e) Defendants have engaged in unfair or unconscionable acts or practices in violation of Haw. Rev. Stat §§ 480, *et seq.*

(f) Defendants have engaged in unfair or unconscionable acts or practices in violation of Idaho Code Am1 §§ 48-601, *et seq.*

(g) Defendants have engaged in unfair or unconscionable acts or practices in violation of 815 Ill. Comp. Stat. Ann. §§ 505/1, *et seq.*

(h) Defendants have engaged in unfair or unconscionable acts or practices in violation of Iowa Code section §§ 714.16, *et seq.*

(i) Defendants have engaged in unfair or unconscionable acts or practices in violation of Kan. Stat. Ann, §§ 50-623, *et seq.*

(j) Defendants have engaged in unfair or unconscionable acts or practices in violation of Me. Rev. Stat. tit. 5 §§ 207; *et seq.*

(k) Defendants have engaged in unfair or unconscionable acts or practices in violation of Mass. Gen. Laws Ch. 93A, *et seq.*

(l) Defendants have engaged in deceptive or fraudulent acts or practices in violation of Minn. Stat. §§ 83l, 325D.44, subd. 1(5), (7) and (13) and 325F.69, subd. 1.

(m) Defendants have engaged in unfair or unconscionable acts or practices in violation of Mo. Ann. Stat. §§ 407.010, *et seq.*

(n) Defendants have engaged in unfair or unconscionable acts or practices in violation of Neb. Rev. Stat. §§ 59.1601, *et seq.*

(o) Defendants have engaged in unfair or unconscionable acts or practices in violation of N.H. Rev. Stat. Ann. §§ 358-A:l, *et seq.*

(p) Defendants have engaged in unfair or unconscionable acts or practices in violation of N.M. Stat. Ann. §§ 57-12-1, *et seq.*

(q) Defendants have engaged in unfair or unconscionable acts or practices in violation of N.Y. Gen. Bus. Law §§ 349, *et seq.* Plaintiffs seek single damages under this statute.

(r) Defendants have engaged in unfair or unconscionable acts or practices in violation of N.C. Gen. Stat. §§ 75-l.l, *et seq.*

(s) Defendants have engaged in deceptive or fraudulent acts or practices in violation of N.D. Cent. Code §§ 51-15-01, *et seq.*

(t) Defendants have engaged in unfair or unconscionable acts or practices in violation of 73 Pa. State. Ann. §§ 201-1, *et seq.*

(u) Defendants have engaged in unfair or unconscionable acts or practices in violation of R.I. Gen. Laws §§ 6-13.1-1, *et seq.*

(v) Defendants have engaged in deceptive or fraudulent acts or practices in violation of S.D. Codified Laws §§ 37-24-1, *et seq.*

(w) Defendants have engaged in unfair or unconscionable acts or practices in violation of Vt. Stat. Ann. tit. 9 §§ 2451, *et seq.*

(x) Defendants have engaged in unfair or unconscionable acts or practices in violation of W. Va. Code §§ 46A-6-101 *et seq.*

251. Plaintiff and the Class have been injured in their business and property by reason of Defendants' unfair or unconscionable acts or practices alleged in this Complaint. Their injury consists of paying higher prices for Opana ER than they would have paid in the absence of such

violations. This injury is of the type the state consumer protection statutes were designed to prevent and directly results from Defendants' unlawful conduct.

SIXTH CLAIM FOR RELIEF

Unjust Enrichment
(Against All Defendants)

252. Plaintiff incorporates the preceding paragraphs by reference.

253. To the extent required, this claim is pleaded in the alternative to the other claims in this Complaint.

254. Defendants have benefited from the overcharges on sales of Opana ER made possible by the unlawful and inequitable acts alleged in this Complaint.

255. Defendants' financial benefits are traceable to Plaintiff's and Class Members' overpayments for Opana ER.

256. Plaintiff and Class Members have conferred an economic benefit upon Defendants in the nature of profits resulting from unlawful overcharges, to the economic detriment of Plaintiff and Class Members.

257. It would be futile for Plaintiff and Class Members to seek a remedy from any party with whom they had or have privity of contract. Defendants have paid no consideration to anyone for any of the benefits they received indirectly from Plaintiff and Class Members.

258. It would be futile for Plaintiff and Class Members to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which they indirectly purchased Opana ER, as those intermediaries are not liable and would not compensate Plaintiff and Class Members for Defendants' unlawful conduct.

259. The economic benefit Defendants derived from charging monopolistic and artificially inflated prices for Opana ER is a direct and proximate result of Defendants' unlawful practices.

260. The financial benefits defendants derived rightfully belong to Plaintiff and Class Members, who paid anticompetitive prices that inured to Defendants' benefit.

261. It would be inequitable under unjust enrichment principles under the laws of each of the states in the United States and the District of Columbia and Puerto Rico for Defendants to retain any of the overcharges Plaintiff and Class Members paid for Opana ER that were derived from Defendants' unfair and unconscionable methods, acts, and trade practices.

262. Defendants are aware of and appreciate the benefits bestowed upon them by Plaintiff and the Class.

263. Defendants should be compelled to disgorge all unlawful or inequitable proceeds they received in a common fund for the benefit of Plaintiff and Class Members.

264. A constructive trust should be imposed upon all unlawful or inequitable sums Defendants received that are traceable to Plaintiff and Class Members.

265. Plaintiff and Class Members have no adequate remedy at law.

DEMAND FOR JUDGMENT

WHEREFORE, Plaintiff, on its own behalf and on behalf of the proposed Class, demands a judgment that:

A. Determines that this case may be maintained as a class action pursuant to Federal Rule of Civil Procedure 23(a), (b)(2), and (b)(3), directs that reasonable notice of this case be given to Class Members under Rule 23(c)(2), and declares that Plaintiff is a proper representative of the Class;

B. Declares that Defendants' conduct violated Section 1 of the Sherman Act, the other state statutes set forth above, and the common law of unjust enrichment;

C. Enjoins Defendants from continuing their illegal activities;

D. Enters joint and several judgments against Defendants and in favor of Plaintiff and the Class;

E. Grants Plaintiff and the Class equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy the Defendants' unjust enrichment;

F. Awards the Plaintiff and the Class damages and, where applicable, treble, multiple, punitive, and other damages, in an amount to be determined at trial, including interest;

G. Awards Plaintiff and the Class their costs of suit, including reasonable attorneys' fees as provided by law; and

H. Grants further relief as necessary to correct for the anticompetitive market effects caused by Defendants' unlawful conduct, as the Court deems just.

JURY DEMAND

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiff, on behalf of itself and the proposed class, demands a trial by jury on all issues so triable.

Dated: July 17, 2014

s/ Robert S. Kitchenoff

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